Food·Drug·Cosmetic Law

Journal

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. On this basis, contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $15 per year, including a handsome binder to hold one year's issues. Single copies are $1.50 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 30, Ill. Printed in United States of America.

September, 1957
Volume 12 • Number 9

Entered as second-class matter December 30, 1948, at the Post Office at Chicago, Illinois, under the Act of March 3, 1879.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . September, 1957

		Page
Reports to the Reader About the Authors . . . Meeting of Food and Drug Men		531
Washington—Action and News In the Food and Drug Administration . . . In the Public Health Service		533
The Rational Use of Chemicals in Food	William W. Goodrich	535
The Food Protection Committee—A New Force in the Field of Food Additives	F. N. Peters, Jr.	541
The Food-Additive Matter — Comments on Proposed Legislation	Edward Brown Williams	553
Public Information Under the Federal Food, Drug, and Cosmetic Act—IV	Wallace F. Janssen	566
Administrative Decisions	C. A. Morrell	577
Federal Meat Inspection	A. R. Miller	585
Christopher Comments . . .	Thomas W. Christopher	592

VOLUME 12 NUMBER 9

© 1957, Commerce Clearing House, Inc., Chicago 30, Illinois
All Rights Reserved

Printed in United States of America

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

Charles Wesley Dunn, New York City, *Chairman;* President, The Food Law Institute; Chairman, Division of Food, Drug and Cosmetic Law, Section of Corporation, Banking and Business Law, American Bar Association; Chairman, Section on Food, Drug and Cosmetic Law, New York State Bar Association; General Counsel, Grocery Manufacturers of America, American Pharmaceutical Manufacturers' Association, and World Medical Association—United States Committee

H. Thomas Austern, Washington, D. C., *Vice Chairman;* General Counsel, National Canners Association

William W. Goodrich, Washington, D. C., Assistant General Counsel, United States Department of Health, Education, and Welfare

Robert E. Curran, Ottawa, Canada, Legal Adviser, Canadian Department of National Health and Welfare

Charles A. Adams, London, England, former Director, Food Standards and Labelling Division, United Kingdom Ministry of Food

Fred Bartenstein, Rahway, New Jersey, Counsel, Merck & Company, Inc.

William E. Fairbanks, New York City, General Counsel, Thomas J. Lipton, Inc.

George Faunce, Jr., New York City, General Counsel, Continental Baking Company

A. M. Gilbert, New York City, Counsel, Best Foods, Inc.

Robert S. Gordon, New York City, General Counsel, National Dairy Products Corporation

Edwin L. Harding, Battle Creek, Michigan, General Counsel, Kellogg Company

Harold Harper, New York City, General Counsel, National Wholesale Druggists' Association

James F. Hoge, New York City, General Counsel, Proprietary Association of America; Counsel, American Foundation for Pharmaceutical Education

Vincent A. Kleinfeld, Washington, D. C., former Food and Drug Law Attorney, United States Department of Justice

George Link, Jr., New York City, General Counsel, Charles B. Knox Gelatine Company, Inc.

Michael F. Markel, Washington, D. C., General Counsel, Corn Industries Research Foundation

Samuel A. McCain, New York City, General Counsel, Corn Products Refining Company

Bradshaw Mintener, Washington, D. C., former Assistant Secretary of Health, Education, and Welfare

Merrill E. Olsen, Chicago, General Counsel, Quaker Oats Company

C. Joseph Stetler, Chicago, Director, Law Department, American Medical Association

William N. Strack, Chicago, General Counsel, Swift & Company

Walton M. Wheeler, Jr., Indianapolis, General Counsel, Eli Lilly & Company

Edward Brown Williams, Washington, D. C., former Principal Attorney, United States Food and Drug Administration

Julius G. Zimmerman, New York City, Attorney, The Coca-Cola Export Corporation

THE EDITORIAL ADVISORY BOARD advises on policies, subjects and authors. It assumes no responsibility otherwise. Its members render this public service without compensation, in order that the FOOD DRUG COSMETIC LAW JOURNAL may comply with the highest professional standards.

Scientific Editor: Bernard L. Oser

Editor of Comments: Thomas W. Christopher

Editor of Canadian Law: Robert E. Curran, Q. C.

REPORTS

TO THE READER

About the Authors

William W. Goodrich, a member of the JOURNAL's editorial advisory board, is Assistant General Counsel for Food and Drugs in the United States Department of Health, Education, and Welfare, at Washington, D. C. A career employee in government service, Mr. Goodrich is well known to our readers as a writer of fine analytical articles.

F. N. Peters, Jr., is chemical-research vice president of The Quaker Oats Company, Barrington, Illinois. He joined the company in 1925, as a research chemist in Miner Laboratories on a fellowship supported by Quaker. Through the years, he has served successively as a chemical salesman for the company, as manager of its technical division and as director of research, before assuming his present post.

Dr. Peters is a member of the Institute of Food Technologists, the American Chemical Society, the American Association for the Advancement of Science, the American Association of Cereal Chemists, Sigma Xi (honorary scientific fraternity), Alpha Chi Sigma (professional scientific fraternity) and Gamma Alpha (graduate scientific fraternity). He holds a degree of Ph. D. from the University of Wisconsin.

Edward Brown Williams, of the Washington, D. C. law firm of Harter, Calhoun, Lishman & Williams, is another of the members of our editorial advisory board. A graduate of the Harvard Law School, Mr. Williams served as a member of the General Counsel's Office, and was Principal Attorney of the Food and Drug Division, in the Federal Security Agency. He has been engaged in the private practice of law since 1946.

This September JOURNAL carries the fourth part of **Wallace F. Janssen's** interesting series on the Food and Drug Administration's policies and practices relating to public-information dissemination. Mr. Janssen is assistant to the Commissioner of Food and Drugs, responsible for reports of FDA activities.

C. A. Morrell presents, in his article on "Administrative Decisions," some of the problems which confront the food and drug administrator. Dr. Morrell is well qualified to write on this topic, for he has been with the Canadian government service since 1930. In 1945, he joined the Food and Drug Directorate; for several years he has been its director.

Before he joined the dominion's government service, Dr. Morrell worked with the West African Yellow Fever Commission in Nigeria. He is a graduate of the University of Toronto, with B. A. and M. A. degrees, and of Harvard University, with a Ph. D.

A. R. Miller is director of the Meat Inspection Division, Agricultural Research Service of the United States Department of Agriculture, with headquarters at Washington, D. C.

The articles of Mr. Goodrich, Mr. Williams, Dr. Morrell and Mr. Miller are adapted from papers which they delivered at the annual meeting of the Division of Food, Drug and Cosmetic Law, Section of Corporation, Banking and Business Law, of the American

Bar Association, held at New York University on July 12.

Also in this issue is the continuing feature "Christopher Comments." It is written by Thomas W. Christopher, associate dean and professor of law at Emory University, in Georgia.

Meeting of Food and Drug Men

A symposium on microscopic-analytical methods in the food and drug industries will be held during the October 15, 1957 meeting of the Association of Official Agricultural Chemists, Inc. Included in the program are:

(1) "Introduction," by Kenton L. Harris, general chairman of the symposium. Mr. Harris is Associate Chief of the Division of Microbiology, United States Food and Drug Administration, Washington, D. C.

(2) "The Food and Drug Inspector Looks at Plant Sanitation" by Kenneth Lennington, chief inspector of the Bureau of Field Administration, FDA. This paper will discuss plant sanitation from the food and drug inspector's viewpoint.

(3) "Programming of Plant Sanitation Practices—A Consultant's Viewpoint," by Maurice Siegel, of Strasburger and Siegel, Baltimore, Maryland. This will be an evaluation of sanitation requirements and the setting-up, by a consultant, of a continuing in-plant sanitation program.

(4) "The Significance of Mold Count in Canned Tomatoes," by William V. Eisenberg, Chief, Microanalytical Branch, Division of Microbiology, FDA. His technical paper will deal with factors influencing the mold count of canned tomatoes, the packing medium in canned tomatoes, and the factors that must be considered in interpreting the Howard Mold Count as an index of the use of rotten tomatoes.

(5) "The Structure and Identification of Hair," by Raymond Myers, Department of Zoology, Colgate University, Hamilton, New York. This will be a discussion of basic hair structure and its practical application in the identification of hair types.

(6) "Laboratory Control in the Canning Industry," by Mary E. Aiken, H. J. Heinz Company, Pittsburgh, Pennsylvania. This paper will discuss the aspects of quality control that are handled by the plant-control laboratory. The viewpoint will be that of a laboratory as a means of maintaining quality control.

(7) "Microanalytical and Microbiological Techniques in Food Plant Sanitation," by V. S. Troy, Continental Can Company, Chicago, Illinois. This paper will deal with the development and application of microanalytical techniques and their effect on over-all production.

(8) "Radiographic Examination of Cereal Grains," by J. Frank Nicholson, microanalyst, FDA. His technical paper will deal with the radiographic technique as applied to cereal grains, the interpretation of radiographs, and the application of this technique to raw material control.

(9) "Practical Aspect of X-ray Testing of Cereal Grains," by Walter Hampe, X-ray Division, Westinghouse Electric Company, Baltimore, Maryland. This will be a companion paper to the one above, dealing with practical considerations of time, cost, etc.

(10) "Integrated Quality Control," by W. W. Prouty, American Stores Bakery, Philadelphia, Pennsylvania. This paper will bring together all of the various aspects of quality control.

(11) "A Lawyer Looks at Section 402a(3)-(4)," by Vincent A. Kleinfeld, attorney, Washington, D. C. This talk by an eminent legal authority on the Federal Food, Drug, and Cosmetic Act will present the attorney's viewpoint.

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

Monthly Report, Issued August 23, 1957.—Unfit and contaminated foods seized in July totaled 560 tons, the Food and Drug Administration announced on August 23.

Included in the seized lots were eight shipments of foods containing injurious chemicals. Fifty-two of the shipments seized consisted of filthy or decomposed foods. More than half of these lots were in good condition when they were shipped, but became unfit in storage, according to FDA.

During the same period, industry voluntarily destroyed 78 lots of food or treated them to prevent their use as food. Administration inspectors reported voluntary improvements in seven factories, to protect food ingredients from contamination.

Fourteen seizure actions in July involved drugs and devices that were substandard, misbranded with false curative claims or shipped without required new-drug or certification clearance.

Identification of Habit-Forming Drugs.—On August 21, the Food and Drug Administration proposed changes in its regulations to provide a more informative and precise identification of habit-forming drugs. No addition or deletion of currently listed drugs would be made, the agency said.

Under the proposal, the use of a trade or proprietary name as the official or common name of a habit-forming drug would be discontinued. Trade names have been used as an official identification of certain drugs in the original regulations because official or unprotected names were not known, FDA explained. Under the proposed changes, trade names and official names would be listed separately.

The regulations would include all the official titles of habit-forming drugs appearing in the standard drug compendia. The chemical names of derivatives and their parent substances would continue to be listed.

The proposed changes would eliminate difficulties in identifying drugs involved in court actions, FDA said.

Interested persons were given until September 20 to file written comments. Notice of the proposed changes was given in the *Federal Register* of August 20. The proposal, in whole or in part, FDA stated, may be modified, rejected or adopted.

Prescription Drugs.—It has been proposed that carbetapentane citrate preparations meeting certain conditions be exempt from prescription-dispensing requirements. Interested persons may submit their views to the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue, Washington 25, D. C., prior to October 13, 1957 (22 *Federal Register* 7319).

Chemical Preservatives.—The time for filing views and comments upon the proposal to amend the definition of 'chemical preservative" (CCH FOOD DRUG COSMETIC LAW REPORTS) and to exempt from labeling requirements (¶ 3050) fruits and vegetables bearing chemical preservatives applied prior to harvest, has been extended until December 1, 1957 (22 *Federal Register* 7382).

In the Public Health Service

Priority Recommendations for Asian Influenza Vaccine.—The Public Health Service announced on September 24 that it has asked manufacturers of Asian influenza vaccine to follow the priority recommendations of state and local advisory committees in filling orders for the vaccine.

The manufacturers already have accepted a voluntary plan for allocating vaccine supplies to each state according to population. The further step now suggested is intended to work toward equitable distribution of the vaccine within the states and communities.

In a letter to each of the producers, Dr. Leroy E. Burney, Surgeon General, noted that the State and Territorial Health Officers Association has suggested the establishment of state and community advisory committees to recommend which groups should be vaccinated first. Dr. Burney requested that the manufacturers "take cognizance of this recommendation in the filling of orders under each State's allocation while the vaccine is in short supply."

He said, further:

"It is suggested particularly that you be guided to the maximum extent possible by the determinations of State and local advisory groups regarding which orders within States and communities should receive priority."

The Public Health Service has recommended generally that vaccinations be given first to those needed to care for the sick and to maintain other essential services, and to patients who constitute a high medical risk.

In keeping with the suggestion of the State and Territorial Health Officers and the Public Health Service, 19 states have already reported the establishment of advisory councils to make recommendations on equitable distribution of the vaccine within their states. Some communities also have followed the recommendation for the establishment of local advisory committees to consider who in the community should be vaccinated first. "We believe the listing of essential personnel within a community can be done best at the community level," Dr. Burney commented.

As details of state and local plans are received, the Public Health Service will furnish information about them to state and territorial health officers generally. "These reports will be passed along simply as information which may contain useful ideas adaptable to other states and communities," Dr. Burney said.

Vol. 12, No. 9 September, 1957

Food·Drug·Cosmetic Law
Journal

The Rational Use of Chemicals in Food

By WILLIAM W. GOODRICH

Mr. Goodrich, at the 1957 Meeting, ABA Division of Food, Drug and Cosmetic Law, in New York City July 12, Examined the "None-of-Your-Business" Approach in Some Proposed Chemicals-in-Food Bills

SINCE Dr. Harvey W. Wiley's time, the Food and Drug Administration has been concerned with the problem of chemicals in food. Perhaps Dr. Wiley's greatest contribution—aside from the task of attracting the needed public attention which brought the Food and Drugs Act of 1906 into being—was to study, expose and eliminate some of the more obvious poisons from foods. Dr. Wiley was concerned with poisons in the crudest sense of the word—with formaldehyde in milk, cocaine in soft drinks, poisonous preservatives in tomato catsup, toxic substances in meats, etc. He pioneered with ways to demonstrate the harmful effects of these poisons, and he dramatized his efforts through his famous "poisons squad."

Today, the facilities and personnel of the Administration are hard at work with the same problem in modern dress—not so much with the acute poisons that result in immediate harm and can readily be identified, but with the more insidious long-time toxic effects of small daily amounts of food chemicals. Congress is considering new legis-

The Author Serves as Assistant General Counsel for Food and Drugs, HEW

lation which at once would relax the long-standing prohibition against unnecessary and avoidable poisonous and deleterious substances in food and would also permit the use of safe amounts of any new chemical. Nothing in the proposed legislation has stirred greater attention among the food and chemical industries—except perhaps the question of judicial control—than the Administration's proposal that new chemicals that are poisonous or deleterious substances must be safe for their intended use and must have some functional value in that intended use.

I would like to discuss with you the significance of the change of national food policy contemplated by this new legislation.

The 1906 Act prohibited any added poisonous or other deleterious substance which might render a food injurious to health.

A *Coca-Cola* case established that all ingredients of a fabricated food are added substances, in the statutory sense. The *Lexington Mill & Elevator* decision ruled that "may render the food injurious to health" meant precisely what it said: If any added poisonous or other deleterious ingredient in a food may possibly injure the health of any consumer of the food—the strong or the weak, the old or the young, the well or the sick—the food was adulterated.

Despite these strongly worded Supreme Court decisions, the fact remained that each food had to be considered separately. Unless the amount of the added poisonous or other deleterious ingredient was enough in each food to render that particular food injurious, no ban was placed upon it. That other items in the diet might contribute some of the same substance, or a related poisonous or deleterious substance, could not be considered. This great weakness was seen in practice, and Congress undertook to eliminate it by enactment of the 1938 law.

The new statute included the so-called per-se rule against all unnecessary and avoidable poisonous and deleterious substances added to foods. It provided that when poisonous or deleterious substances were required in the production of a food or could not be avoided in good manufacturing practice, safe tolerances should be established for them. We were clearly authorized to take into account the extent to which the chemical was required or unavoidable, and the several ways in which the consumer may be affected by the same or any other poisonous or deleterious substance.

The rule of reason established by the existing law was founded on great caution and a very strong public prejudice against "chemicals." The answer to any proposed use of a poisonous or deleterious substance was an emphatic "no," unless it could be shown that the chemical was required or unavoidable.

Insecticidal, Fungicidal, and Other Agricultural Chemicals

Over the years, only the insecticidal, fungicidal, and other agricultural chemicals met this strict test. No tolerance has ever been established for any other kind of poisonous substance. Even in the case of the insecticidal sprays—which Congress plainly indicated it intended to permit under the per-se rule—literal reading of the statute would have made it difficult to justify a variety of agricultural chemicals with different degrees of toxicity, all intended to attack the same agricultural pests.

In 1954, Congress passed special legislation on the pesticide chemicals, and substituted, for the "required in production" test, the test of agricultural usefulness as determined by the Secretary of Agriculture. Unless some rational agricultural utility can first be shown, we are relieved from considering the question of tolerances. In considering agricultural usefulness, the Secretary of Agriculture must tell us how much residue is likely to remain when the pesticide is used to accomplish the desired agricultural purpose. We do not tolerate residues of pesticide chemicals above the levels needed in rational agriculture. National policy there has been to permit what is needed if that amount can be shown safe. If the amount cannot be shown safe, we need not tolerate it despite its established usefulness. Higher amounts need not be tolerated, even though apparently safe, if there is no sound agricultural reason to use the higher levels. In brief, if seven parts per million of a pesticide is all that is needed for sound agricultural

practices, we fix the tolerance at seven, though 20 p. p. m. might be considered safe. Lacking a reason for a higher tolerance, there is no point in tolerating the excess poisonous residues, however slight the risk involved.

Other Added Poisonous or Deleterious Chemicals

As to all other added poisonous or deleterious substances in food, the per-se rule of exclusion still prevails. Over the years, no chemicals met this test. In the early forties, proposals were made to us to establish a tolerance for monochloracetic acid in wine. This chemical has a toxicity comparable to bichloride of mercury. The proponents of the tolerance proposed the use to prevent fermentation of certain sweet wines. They represented that the chemical would prevent spoilage and consequent economic loss. They were told frankly that the Food and Drug Administration would not consider this use one that is "required in production," because wine had been produced for generations without a preservative, and proper sanitary measures in production and handling would make chemical preservation unnecessary. The petition was, nonetheless, scheduled for a hearing, but it was withdrawn when the industry was unable to get ready by the assigned date.

The matter was dropped, and a number of regulatory actions were taken against foods—beverage bases, mayonnaise, etc.—containing this chemical. About the same time, the *Commonwealth Brewing* case was tried, with jury instructions to the effect that any amount of fluorides in beer was an adulteration if the jury found the fluoride to be a poisonous or deleterious substance that was not required in production or was avoidable in good manufacturing practice. The evidence for the government compared the fluorides to well-known acute poisons, and showed that beer had been produced for generations without the chemical. Somewhat later, a chemical manufacturer proposed the use of dimethyl dichlorosuccinate as a mold inhibitor on cheese wrappers. The petition was rejected because the evidence in the petition showed the chemical to be a poisonous substance. "Required in production" could not be established because wrapped cheeses without antimycotics were in widespread production and sale. Recently, two proposals have been advanced to establish a tolerance for a poisonous antioxidant in dehydrated alfalfa and a poisonous sprout inhibitor for potatoes and onions. In these cases it seemed fairly clear that the chemicals served an agriculturally useful purpose

—indeed, the Department of Agriculture so certified as to the antioxidant. While these chemicals are still under consideration, they have not yet been shown to meet the strict rule of exclusion of unnecessary and avoidable poisons.

Some of the proposed bills on chemicals in foods would scrap the per-se test as the rule of reason in permitting poisons. The industry-supported proposals in the last session of Congress would go the whole circle back to the point where any chemical—even a notorious poison such as formaldehyde—could be added to any food for any real or fanciful reason or for no reason at all. They would say that so long as the proposed level of use of formaldehyde involved no health hazard, it is none of the Department of Health, Education, and Welfare's business why the proponent of the chemical wants it used. The argument is that if safety is shown, that is all that is needed, and that business considerations will be enough to sell the chemical or to prevent its sale.

The Food and Drug Administration's files are full of evidence that this philosophy is not acceptable to the average consumer. The public doesn't support the purposeless addition of chemicals to its foods. Yet we believe it does support the rational use of chemicals to simplify food-processing and to improve the food supply. It wants only the assurance that there is a good reason for the addition of the chemical and that the chemical in the diet is safe. Our correspondents will not accept the idea that we should allow the indiscriminate use of small amounts of known poisons in our foods only because, on the basis of tests with laboratory animals, these small amounts appear to be safe. They want to know what justification there is for using the chemical, not that there is no positive reason for not using it. There is reason enough for not using it if it is a poisonous substance. Public opinion will be satisfied only by a rational justification based on considerations of food technology or consumer benefit coupled with assurance of safety of the proposed use.

So much for the public attitudes as they are reflected to us by our consumer contacts. These attitudes find support among the scientists and public health officials concerned with the problem of chemicals in foods. These scientists, in the most solemn statement of policy on the factors to be considered in permitting the addition of chemicals to our foods, have said that the proposed use of the chemical must be both safe and beneficial to the consumer. They explain this by saying that we cannot be sure—using present-day methods of safety-testing—

that a proposed use of a chemical will be absolutely safe. Our methods do give us an assurance of safety which removes all reasonable doubts. There remains, however, a gap between reasonable doubt and absolute certainty which science cannot close. Because of that, the Food Protection Committee has said that a chemical substance should not be added, even though its safety is shown by the best available scientific means, unless the chemical is also beneficial to the consumer.

Interpretation of "Beneficial to Consumer"

This is a philosophy with which food officials and our scientific advisors agree. We interpret "beneficial to the consumer" to mean that a use benefits him directly, in terms of product improvement or food convenience, or indirectly, in terms of improvement in food processing, storage, packing, or other steps in moving the food from its raw state to the dinner table. To us, that is what is meant by "functional value," as the term is used in the Department-sponsored bill. We are willing to accept the idea that the reason for adding a chemical is none of our business under this law when the chemical is an innocuous one, but we cannot accept the idea of the pointless addition of poisonous or deleterious substances to our food. We do not think it out of line to ask why the chemical is proposed when the scientific data shows it to be a poison. We cannot believe that any reasonable food manufacturer would not ask himself "why" before he added a poison to his products, and we are certain that the consumer would want to know why. In our thinking, the reason for the proposed use is a relevant factor in permitting the chemical so long as scientific methods do not provide absolute assurance of safety.

Why not continue with the "required in production" and "unavoidable in good manufacturing practice" test? This test is not realistic; few, if any, chemicals can meet it when it is applied as written; and it needlessly prevents the use of technologically important food chemicals at levels as to which there is no reasonable doubt of safety.

The Department's bill was drawn to provide a rational basis for the use of chemicals in foods that could be accepted by food manufacturers, chemical manufacturers, scientists and consumers alike as a proper rule under which food technology may progress without endangering the public health. The none-of-your-business approach is unacceptable to scientists, to consumers and to public health officials. We believe it equally unacceptable to responsible business people. [The End]

The Food Protection Committee– A New Force in the Field of Food Additives

By F. N. PETERS, JR.

The Author Notes That the Food Protection Committee May Be the Vital Ingredient, Lack of Which Has Prevented—in the Past—a Reasonable, Judicial Approach to Orderly Development and Improvement of Food Law

HOUSE RESOLUTION NO. 212, introduced on March 25, 1957, proposes:

> That a select committee be appointed to conduct a full and complete investigation and study of the use of chemicals and other additives in food and medicine and beverages with a view to ascertaining what deleterious effects such chemicals have on human life and health.

About seven years ago, another select committee of the House of Representatives, popularly known as the Delaney Committee, investigated this same subject, heard over 200 witnesses and introduced several bills to amend the Federal Food, Drug, and Cosmetic Act. In each succeeding Congress, more-or-less similar bills have been introduced, and the present one is no exception. No less than five such bills have been proposed in the House, and S. 1895—a duplicate of H. R. 6747—has been introduced in the Senate.

To an impartial and curious observer, unfamiliar with the historical background, the reasons for the long succession of failures to obtain amendments satisfactory to the Food and Drug Administration might seem worthy of study. This would develop the fact that there are from 500 to 700 additives used by the food industry to a greater or lesser extent. This number includes such well-known "chemicals" as salt, soda, corn sugar, leavening agents, pepper, and

Dr. Peters Is a Vice President of the Quaker Oats Company, Located at Barrington, Illinois

other spices, as well as less-known materials useful for delaying the development of rancidity, for prevention of mold growth, and as emulsifiers and humectants.

Further study would show that many of these additives are considered necessary by manufacturers and regulatory agencies alike. In a copyrighted interview, Mr. George P. Larrick, Commissioner of Food and Drugs, is quoted (*U. S. News & World Report*, May 31, 1957, page 76) as saying:

> If you are going to have cake mixes, breaded shrimp, fish sticks, and many other foods almost ready to eat, you've got to add things to keep them from getting too dry, to keep them from caking, to maintain the color, to preserve and to emulsify and prevent separation. You have a great many technical needs.

In answer to a question as to whether it is more dangerous to eat today than it was in the days when practically all food was prepared in the home, the Commissioner said: "In my opinion it is much safer to eat today."

Further investigation would unearth evidence that the American food manufacturer is using food additives and the newer knowledge of technology without hazard to public health. It appears that if demonstrable damage to the public health or illnesses arising from ingestion of food additives were the sole criteria for proposing amendments to the food laws, there would be no such amendments. Why, then, the recurrent demand for additional legislation?

The first reason given is that the present law does not specifically require testing of ingredients before use. There is no legal requirement that the administrator shall be notified in advance of the use of

a new additive. The administrator cannot prevent the use of an additive unless he can prove it is deleterious or harmful. The great majority of manufacturers do discuss their proposed new ingredients with food and drug officials, but the latter will do no more than say they know of no reason why the additive should not be added. The law does not give them the authority to either approve or disapprove of its use.

With this much information, our impartial observer might suggest the adoption of a simple amendment requiring the pretesting of all new food additives and submission of data to the Food and Drug administrator prior to the use of the chemical. If the administrator felt such data were inadequate to establish safety, he would so advise the manufacturer. No responsible company would dare use an additive if it were in receipt of an adverse opinion from the administrator or, at least, not until it had done considerably more testing and had had additional conferences with the administrator. It is reasonable to suppose that large and small companies alike would welcome the constructive advice and counsel of the experts in the Food and Drug Administration. There is reason to believe there is a genuine desire to put the administrator in a position where he can advise the manufacturer regarding adequacy of testing and safety of use.

What Administrator Seeks to Do

But such an amendment is not satisfactory to the Food and Drug Administration. One reason is that the manufacturer could use an additive in spite of the administrator's criticism, and then the latter would have to prove toxicity in order to prevent its use. He wishes, therefore, to remove the burden of proof of toxicity from the government and require the manufacturer to assume the burden of proof of safety.

A food processor, being convinced that no responsible company or anyone with good conscience would use an additive in the face of a negative report from FDA and knowing that absolute safety can never be proven, begins to look for hidden motives in the proposals submitted by the Administration. The more he tries to understand the position of the agency, the more suspicious he becomes. He does not object to pretesting; he already does it. His very existence depends upon public acceptance of his product. The surest way for him to lose public favor is to be careless of the public welfare. A government official may be up for election or appointment every two

to four years, but the products of the food manufacturer are on trial every time a consumer enters a store. No food-control official has any more cogent reasons for protecting the public health than does the food processor.

Feeling of Misunderstanding and Mistrust

The Administration, being perfectly sure of the purity of its motives and the correctness and fairness of its decisions, cannot understand the reluctance of industry to accept the proposed amendments and begins to wonder whether industry can be depended upon to make a conscientious effort to protect the public health; thus, an atmosphere of misunderstanding and mistrust develops.

It is impossible to assign to a single cause the development of this feeling, but two cases will serve as examples. Virtual miracles had been performed with DDT in tropical areas during World War II, and its peacetime uses developed rapidly. Most persons assumed it was perfectly safe; it was a rude shock to learn that this product could produce long-term damage if improperly used. The reaction to this surprise was to blame industry and to charge it with gross negligence and wanton disregard for public health. To a lesser extent, censure was directed to FDA and other agencies. In defense, these agencies—possibly as surprised as anyone else at the disclosure of toxicity—claimed there was inadequate authority to deal with such situations.

Attacks Growing Out of Bread-Standards Testimony

The bread-standards hearings produced testimony which was seized upon by some to accuse the food industry of disregard of the public welfare. Many of the thousands of pages of the record of this hearing were devoted to alleged toxicity of chemicals not even proposed for use in foods; publicity seekers, irresponsible journalists, and food faddists found much in the hearings to serve their purposes. The food industry and the food and drug officials became targets for their attacks, and pressure for additional legislation increased. Some attacks grew out of testimony before a House investigating committee. An article appeared in a nationally distributed magazine, entitled "Peril on Your Food Shelf." The introduction read as follows:

> In this article, the head of a Congressional committee reveals evidence that hundreds of untested and unproved chemicals, in the hands of irresponsible food manufacturers, are threatening the health and even the lives of our families.

Other articles of similar nature appeared under the titles "Are We Eating Poisoned Foods?" and "Bread—The Phony Staff of Life." In an August 1, 1951 report by the Senate Committee on Forestry and Agriculture, the statement appeared that "many of the flours contain phosphorus, fluorine, silicon, alum, nicotinic acid, potassium bromate, and a score of other poisonous drugs."

Untrue and silly though such statements are, they are alarming to an uninformed public.

This, then, is a partial background for the present proposals to amend the Food, Drug, and Cosmetic Act, and may help explain why a competent government agency and an industry that has given us the safest food supply in the world do not always work in complete harmony. But at the very time this feeling of mistrust and suspicion was developing, an entirely different group was coming into the picture.

Chartering of National Research Council

In 1916, a National Research Council was inaugurated under the Congressional charter of the National Academy of Sciences for the purpose of providing an independent group of scientific counselors to the government. It is not a government agency and is dependent on endowments, grants or actual cost contracts for administrative expense. All funds administered must be dedicated to the public and serve for the advancement of science or its application to public policy and welfare. The council administers, and is responsible for the affairs of numerous committees, panels and boards comprising many of the most competent scientists of the country. The Food and Nutrition Board is one of these groups.

About 1947 or 1948, this board became concerned with the possibility that pesticidal residues might find their way into foods. An *ad hoc* committee on food protection was appointed in October of 1948 to look into this matter. It was to determine the hazards, if any, to public health, arising through the increasing use of pesticides, as well as food additives. This committee met several times during 1949, and it sponsored a meeting of industry representatives, governmental agencies and trade associations, which was held on December 29, 1949. The consensus of this group was that unlimited and inexpert use of insecticides conceivably could present a public-health hazard but, also, it was recognized that production, preservation and delivery of foods in adequate quantities required the use of insecticides, as well

as an increasing number of food additives. However, there were no generally recognized or approved standards for determining the hazards of these products. Analytical methods were inadequate to the situations present by the use of some of these products. Therefore, everyone agreed that more scientific data were necessary, but how to obtain these was not clear.

Industry's Data Not Acceptable to Government Agencies

Many industrial concerns were capable of obtaining, and had obtained, reliable data on their products, but these were not generally acceptable to federal agencies. Again, it was a case of suspicion and mistrust. If industry's data were not acceptable, where could such be obtained? A research foundation supported by industry might be an answer.

However, at the Washington meeting it was decided that a committee of the Food and Nutrition Board should study the problem and determine whether it could be defined and separated into categories for the solution of which specific recommendations might be made at a later date. It was recognized that the operation of such a committee, as well as its success, would require not only money, but moral support from industry, trade associations, federal agencies, and other interested parties. Hence, an industrial organizing committee was formed to make further studies and, after considering various proposals, made the following recommendations:

That a food protection advisory committee, with a full-time secretary, be set up within the framework of the National Research Council.

That the membership of the committee be composed of individuals with the scientific competence to advise on the various phases of food protection and include a representative from the Public Health Service, the Food and Drug Administration, and the U. S. Department of Agriculture.

That the function of the committee be (1) to consider and evaluate available scientific data on chemicals proposed for addition to food, or for use that will affect food products; (2) to organize such data for use, and to point out missing data; (3) to recommend models of further experimental study, kinds of evidence, or data required; (4) to organize panels of scientists and experts competent in the various phases of the problem to advise the committee as requested.

In the development of the final structure of the Food Protection Committee, representatives of the government agencies named in the recommendations were not included in the committee proper. Instead, a liaison panel was established with representatives of industry, gov-

ernment agencies, scientific societies, trade associations, and foundations making up sections of the panel.

A permanent Food Protection Committee was established by the National Research Council in 1950, composed of the following scientists: H. E. Longenecker, chairman, dean of the Graduate School of Research in the Natural Sciences, University of Pittsburgh; William J. Darby, head, department of biochemistry, and director, Division of Nutrition, Vanderbilt University School of Medicine; George C. Decker, head, Economic Entomology Section, State Natural History Survey and Illinois Agricultural Experiment Station; Donald E. H. Frear, professor of agricultural and biological chemistry, Pennsylvania State College; C. E. F. Guterman, director of research, New York State Colleges of Agriculture and Home Economics, and director and professor of plant pathology, Cornell University Agricultural Experiment Station; David B. Hand, professor and head, Division of Food Science and Technology, New York State Agricultural Experiment Station; Elliott A. Maynard, assistant professor of pharmacology and toxicology, School of Medicine and Dentistry, University of Rochester; L. A. Maynard, director, School of Nutrition, Cornell University; George L. McNew, managing director, Boyce Thompson Institute for Plant Research; and R. Blackwell Smith, Jr., associate professor of pharmacology, Schools of Pharmacy and Medicine, and dean, School of Pharmacy, Medical College of Virginia.

The committee, while receiving its financial support from industry and consulting at frequent intervals with members of an industry committee representing these supporters, is solely responsible for its final judgments, conclusions, and preparation of reports, and is subject only to the Food and Nutrition Board of the National Research Council for its public releases.

First Committee Publication—1951

The first of these publications was issued in December, 1951, and was entitled *Use of Chemical Additives in Foods.* Recognizing that a great deal of misunderstanding regarding the food-additives problem existed, this report pointed out that the constituents of foods themselves are chemicals which

> . . . may be classified as carbohydrates, fats, proteins, minerals, water and accessory factors such as vitamins. . . . In addition to the natural variations in chemical composition of foodstuffs, chemicals may be incorporated during the growing or during the storage and processing of the food. These chemicals may

be described for convenience as "additives." When they are introduced to preserve or improve the quality of the product they are known as intentional additives because they are purposely added to serve a specific need.

The statement then went on to explain why chemical additives are used, the necessity for the use of pesticides, and the benefits to be obtained from them. In connection with the value of additives, the following quotations are pertinent:

> The enrichment of flour and bread with essential nutrients has improved the diet of the American people. The controlled addition of iodides to table salt to prevent goiter and fluorides to drinking water to help prevent tooth decay have long been advocated by responsible groups.

> Uniform products are expected by the public and chemicals are used to help attain this uniformity. Examples of such use of chemicals are the addition of naturally occurring materials such as phosphates and citrates to evaporated milk, minute amounts of dyes to color margarine or to color butter to compensate for seasonal variations, and flavoring agents, both natural and synthetic, to control flavor intensity in many processed foods. Consumer dissatisfaction would result if, for example, brand name products differed in flavor or color with every package.

> Chemical additives are needed to preserve some foods and their use has long been accepted practice. Spicing and smoking of food products are typical examples of food preservation. . . . sodium propionate is frequently used to prevent the molding of bread. Antioxidants may be added to fats and fatty foods to prevent rancidity. Under no circumstances can preservatives be justified as a substitute for good sanitary practice. It is obvious, however, that the cost of food would be increased and its distribution would be handicapped by omitting them.

It is particularly interesting to note that these statements were released by scientists after careful consideration of all the facts. Also, they appeared about the time the public was becoming greatly alarmed as a result of some of the misleading articles mentioned above.

Other Publications—1952-1956

This publication was followed in 1952 by another entitled *Safe Use of Chemical Additives in Food.* In this booklet, ground rules were laid out for evaluating the safety of chemical additives and the hazards encountered in the use of pesticides. Later publications were devoted to considerations of safety of specific additives. These were entitled *The Safety of Mono- and Diglycerides for Use as Intentional Additives in Foods; The Safety of Polyoxyethylene Stearates for Use as Intentional Additives in Foods;* and *The Relation of Surface Activity to the Safety of Surfactants in Foods.* An *Annotated Bibliography of Analytical Methods*

for Pesticides containing references to both published and unpublished works describing analytical methods for determining the presence of many of these products was issued in two sections in 1952 and 1954. In August of 1955, a report was made on "The Safety of Artificial Sweeteners for Use in Foods." This included information on the toxicology and evaluation of saccharin, which has been used in dietary foods for many years, and on the newer nonnutritive sweeteners known to chemists as "cyclamates." The conclusion was reached that "there is no evidence that use of the nonnutritive sweeteners, saccharin and cyclamate, for special dietary purposes is hazardous."

Year after year, the charge has been repeated that hundreds of untested chemicals are used in foodstuffs. No one really knew how many there were, what they were, or how much of any of them was used. The answers to these questions are obviously important. The Food Protection Committee referred this problem to its food technology subcommittee, which—with the cooperation of many industrial concerns, trade associations and governmental agencies—collected material which was published in 1956 under the title *The Use of Chemical Additives in Food Processing*. This is a 91-page report listing, in 12 groups, every additive for which authentic evidence of use was developed. Where the information was available, the levels of use for each of these are given.

Ill-Considered or Hasty Judgments re Food Additives

The introduction calls attention to some of the unfortunate results that arise from ill-considered or hasty judgments, regarding the complex subject of food additives, in these words:

> The widely publicized Delaney Committee statement has caused apprehension as to the safety of processed foods. Considerable stimulus has been given to the adoption of food practices that are without economic or scientific justification. Evidence of this can be found in the efforts of consumers to obtain, for example, oranges grown without chemical fertilizer, raisin grapes grown without insecticides, or bread made from unbleached flour.
>
> The mere statement that a definite large number of chemicals is used in foods is uninformative or even misleading. It is necessary to know what the chemicals are, the extent to which they are used, and the foods to which they are added. Many of the estimated 704 chemicals (Note: This is the figure reported by the Delaney Committee. The true figure seems to be closer to 550.) are used in such minute amounts and in such infrequently consumed foods that negligible quantities are involved. Some such as salt, baking soda, vinegar and vegetable colors are used in every kitchen. Others are used in such manner that they disappear completely from the food before it is consumed.

Classifications in 1956 Report

The first section deals with the technological benefits of intentional additives. Foods are divided into the following six classifications: cereal products; processed fruits and vegetables; beverages; dairy products; confections, sweeteners and sugars; meat products and fats. The types of additives that are used with each of these classifications are described. For example, the introduction to the section on cereal products is as follows:

> Chemical additives are employed to enhance the nutritional value of cereal foods, to improve their cooking or baking qualities, to increase consumer acceptance, and to retard the onset of deterioration. The additives used in cereal products include vitamins and minerals, flour bleaching and maturing agents, bread improvers, emulsifying agents, leavening agents, flavoring materials, mold and rope inhibitors, and antioxidants.

The functions of the additives used with each of the other five groups of foods are described in a generally similar manner.

This publication contains the most complete available tabulation of additives used in processed foods. The fact that much of the information came through voluntary reports from industry might well be taken as evidence the food industry believes it has nothing to hide. Of the 550-odd additives listed here, about 300 are flavoring ingredients. Probably some additives listed in the book are not used, because included in these lists are all of the products previously approved for use in foodstuffs by FDA and by the regulations for meat products and fats put out by the Meat Inspection Branch of the Department of Agriculture. It is not certain that all of the permitted ingredients are actually being used. Some may be used only seasonally, or by a few companies in one section of the country and not by others in the same industry.

Reports Emanating from International Conference on Cancer

Last fall, many newspapers and magazines carried stories arising from an international conference of cancer experts held in Rome. These stories gave the general impression that carcinogens are being added deliberately to American food. Such statements lead to a clamor for laws prohibiting additives of any kind and to a loss of public confidence in the integrity of the food industry. At the request of the industry committee, the Food Protection Committee in December, 1956, issued a statement on the subject. It was given to many journals

and the wire services. The statement was not sensational—scientific reports seldom are—but it was factual and reassuring to anyone willing to take the time to study it. It is the best rebuttal the food industry has today to the charge it is deliberately adding carcinogens to foods.

The Food Protection Committee has had an *ad hoc* committee on dietary carcinogens for the past two years. In 1957, a subcommittee on carcinogenesis has been recommended and undoubtedly will be active during the remainder of this year. Plans for additional conferences on this subject are already formulated.

At the present time the Food Protection Committee comprises William J. Darby, chairman, head, department of biochemistry, and director, Division of Nutrition, Vanderbilt University School of Medicine; David B. Hand, vice chairman, UNICEF, United Nations; Paul R. Cannon, chairman, department of pathology, University of Chicago; Herbert E. Carter, head, department of chemistry and chemical engineering, University of Illinois; J. M. Coon, professor of pharmacology, The Jefferson Medical College, Philadelphia; George C. Decker, head, Economic Entomology Section, State Natural History Survey and Illinois Agricultural Experiment Station; Elliott A. Maynard, associate professor of pharmacology and toxicology, School of Medicine and Dentistry, University of Rochester; Emil A. Mrak, chairman, department of food technology, University of California; R. Blackwell Smith, Jr., president, Medical College of Virginia; and Paul E. Johnson, executive secretary.

Active Subcommittees of Committee

There are four active subcommittees working in the fields of (1) food technology, (2) pesticides, (3) toxicology and (4) carcinogenesis. These four subcommittees include, in addition to members of the Food Protection Committee, other scientists from various universities, governmental agencies and industries throughout the country. As already indicated previously, financial support for the activities of the Food Protection Committee comes from voluntary subscriptions by industry.

The committee, comprising eminent authorities in nutrition, food technology, physiology, toxicology, biochemistry, and various other medical fields and related sciences, is a great calming influence in the polemics of food additives. Here is a group of technically competent men with one objective—the determination and publication of the

truth. Thus, industry and regulatory officials have this group for help and guidance in a complex field, and on several occasions FDA has requested and received aid from the committee. It is probable that the value of this aid suggested the creation of scientific advisory groups described in several of the proposed amendments and which are a part of Public Law 518.

Will Committee Bring About Agreement as to Legislation?

The Food Protection Committee might be the missing ingredient which has prevented, in the past, a reasonable, judicial approach to the orderly development and improvement of food laws. This is not to suggest that the committee should ever mediate opposing claims regarding needed legislation. This is a field foreign to the activities of the Food Protection Committee. But the fact remains that, although both the food industry and FDA desire to maintain the integrity of the food supply, they are not agreed upon the form of legislation. One reason for this long-standing disagreement is that there are areas where the real truths are not known or, at least, are not always understood. Insofar as these truths can be and are ascertained by scientific investigation, the areas of disagreement will become less, and ultimate agreement will come closer. This independent fact-finding group of scientists has already charted areas wherein the food industry, FDA and public-health authorities have developed a common viewpoint; as further facts are disclosed by scientific research, the proper legislative action will become much clearer than it is today.

George Washington is credited with a statement that goes somewhat as follows: "Let us raise a standard to which the wise and honest may repair."

In the field of food additives as they may affect public health, the Food Protection Committee is such a standard. It thus deserves widespread recognition and support by all those segments of our economy which are interested in nutrition and public welfare.

[The End]

• FOOD PRODUCTS—PRICE DISCRIMINATION •

A company which processes and packages dried foods is charged with selling dried peas and beans to a grocery chain for resale by its retail stores in a specific area at prices substantially lower than those charged other direct-buying retailers competing with the chain in the area. Also, it is alleged that the prices to the chain are lower than those charged wholesalers who resell to the chain's retail competitors. (Released September 3, 1957.)—CCH TRADE REGULATION REPORTS ¶ 26,688.

The Food-Additive Matter—

Comments on Proposed Legislation

By EDWARD BROWN WILLIAMS

This Paper, from the July 12 ABA Meeting in New York City, Suggests That the Vast FDA Authority over the Food Supply Proposed in H. R. 6747 Seems Clearly to Justify an *Adequate* Review Function to be Vested in the Courts

THESE COMMENTS RELATE to some of the basic provisions of proposed food-additive legislation now before Congress. I proceed with more than a little hesitation because of the fine and thorough treatment this subject has heretofore received. My observations will reflect, however, an approach to the matter which differs largely from others with which I am familiar. I hope that some of you will find it of interest.

Definition of "Chemical Additive"

The definition of the subject matter of the proposed legislation is, of course, a critical factor. The Administration bill,[1] introduced by Chairman Harris of the Interstate and Foreign Commerce Committee of the House of Representatives, defines the term "chemical additive" to include any substance which may become a component, or otherwise affect the characteristics, of any food "if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its toxicity or other potentiality for harm, as having been adequately shown through scientific procedures or through prolonged use in food to be safe for use under the conditions of its intended use" (proposed new Section 201(s) of the Federal Food, Drug, and Cosmetic Act).

This definition is the basic test of the jurisdiction of the Food and Drug Administration which would be established by the proposed

[1] H. R. 6747, 85th Cong., 1st Sess.

Mr. Williams, Who Is Engaged in Law Practice in Washington, D. C., Is a Member of the Firm of Harter, Calhoun, Lishman & Williams

legislation. If an additive is not generally recognized as safe by qualified experts, it may not be used unless it is cleared under the usually costly and time-consuming procedures which will be instituted by the Food and Drug Administration.

This is also, in its essentials, the test of whether a drug is subject to the new-drug provisions of the Food, Drug, and Cosmetic Act (Section 505).[2] Section 201(p)[3] defines the term "new drug" to mean:

> Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . .

A similar definition delineates the scope of the pesticide-chemicals amendment to the Act.[4]

The propriety of the definition of "new drug" has been questioned on various grounds, including that of constitutionality. I shall confine my remarks, with respect to its suitability for food-additive legislation, to practical considerations and to legal factors other than those of constitutionality.

Fundamentally, it would seem that whatever merit this jurisdictional test may have in the relatively narrow fields of new drugs and pesticide chemicals, it is unrealistic as a criterion for determining whether vast numbers of food additives and food-packaging materials (existing today or yet to be created) must be formally approved by the government before they may be used.

Reducing the matter to simple terms, it seems evident that the "qualified experts" referred to in the proposed legislation will, in most

[2] 21 USC Sec. 355.
[3] 21 USC Sec. 321(b).
[4] Sec. 408(a), 21 USC Sec. 348(a).

cases of new additives, in fact be without qualification to pass upon the question of safety, since the new substances or new uses of them will not be generally known to such experts. Consequently, such substances may not be regarded as safe for use if the "generally recognized" test is applied to foods as it is to new drugs and to pesticide chemicals.

The effect would be, therefore, that the decision as to whether a particular substance must be submitted to the Food and Drug Administration for clearance in accordance with the statutory formalities would be arrived at not upon the basis of the evidence of safety accumulated by the person proposing to use it, but upon the basis of the supposed opinions of an undefined group of scientists or other "experts." Thus, the merits of the question of safety need not be reached in determining whether an additive is subject to the legislation. In the event of litigation on this jurisdictional question, the inquiry of the court would be directed basically to the question of whether the experts generally recognized the additive as safe rather than to actual experimental evidence of safety developed by the industry.

In practice, it may be anticipated that the experts whose opinions would be controlling would be members of the staffs of medicine and pharmacology of the Food and Drug Administration.

This jurisdictional aspect of the proposed legislation is a critical one which has not, it seems to me, received the consideration from industry which its significance demands. There should be a decision upon the facts by the Food and Drug Administration in determining jurisdiction under this far-reaching legislation, and not simply a recourse to the frequently illusory test of general recognition. I think that a realistic evidentiary basis for such determinations would offer a practical solution to this question.

It is evident that industry must assume the burden of affirmatively clearing any chemicals which it proposes for food use. For that reason, it would not be enough to require simply that industry show adequacy of testing by a preponderance of the evidence—the test which guides the jury in most civil actions at law. "Preponderance of evidence" means only "greater weight of the evidence" or "evidence which is more convincing to the jury as worthy of belief than that offered in opposition thereto." The courts usually hold that an instruction to the jury that it must be satisfied, certain or convinced is erro-

neous because it requires too high a degree of proof. Where the evidence is evenly balanced, the party having the burden of proving his case by a preponderance of the evidence must fail.[5]

If, for example, the Food and Drug Administration itself were required to show by a preponderance of the evidence that a proposed additive had not been sufficiently tested to demonstrate its safety, the industry would prevail if the evidence were considered by the court as evenly balanced. Such a standard of proof would hardly be adopted by Congress even if the industry should ask for it.

A more demanding standard of proof employed in certain types of civil cases requires that, for a party to prevail, he must establish his case by "clear and convincing" evidence, a showing which is plain and convincing beyond reasonable controversy.[6] This test seems appropriate to the kind of legislation with which we are dealing insofar as the burden of proof to be placed upon the industry is concerned.

If this view is sound, it would seem that a reasonable alternative to the "generally recognized" test would be a definition of "food additive" to include any substance which may become a component of food unless such substance is generally recognized as safe by qualified experts or unless there is clear and convincing evidence upon the whole record that its use under the intended conditions will offer no reasonable possibility of hazard to the public health. Thus, a substance would be excepted from the definition if it could be shown by clear and convincing evidence that it had been adequately tested to demonstrate its safety.

There seems to be no reason to discard the "generally recognized" test as an alternative method of establishing whether a substance falls within the scope of the legislation. A proponent of the use of a substance not generally recognized would always be entitled to show that its use would be safe, by coming forward with clear and convincing evidence to that effect. The Food and Drug Administration would then decide upon the question of the adequacy of testing, but it could not base its determination upon its view of whether the substance was "generally recognized" as safe by experts. It could, of course, and doubtless would, in many instances, obtain the opinions of experts with respect to the adequacy of the evidence submitted to it.

[5] 20 American Jurisprudence, "Evidence," Secs. 1249-1250.

[6] Work cited at footnote 5, Sec. 1253.

Under such a statutory structure, if the government should bring a legal proceeding against the use of an additive, it would prevail unless the court were persuaded by clear and convincing evidence that the additive had been adequately tested for safety and, therefore, was excepted from the definition. The public interest would thus be protected.

In its fundamentals, this approach would result in an evaluation of the available evidence by the Food and Drug Adminstration itself rather than simply a reliance upon the too-intangible "generally recognized" test. The suggestion is premised, as I have indicated, upon the belief that industry should not be required to submit to the proposed clearance procedures and to undertake extensive studies of the toxicological and pharmacological characteristics of a new additive, where there exists clear and convincing evidence of its safety, solely because the additive or its intended use is not generally known to the experts and, therefore, could not be generally recognized by them as safe.

I want to emphasize that such a jurisdictional test would mean that where food and drug authorities refused to accept the evidence of a proponent of an additive as sufficient to exclude it from the legislation, the proponent could plot his future course with the knowledge that, should the Administration bring legal action against him, the question of jurisdiction would be determined upon the basis of a real evidentiary test. Ordinarily it would not come to that, as we all know.

This suggestion does not, of course, relate to the scope of review of administrative findings after hearing. It concerns only the problem of when an additive must be subjected to the procedures for determining whether a regulation should issue establishing the conditions under which it may be used. The statutory review question is considered later.

"Grandfather Clause"

One other aspect of the definition of "chemical additive" in the Administration bill should be mentioned: The bill excludes from the term "chemical additive" any substance used in accordance with a sanction or approval granted prior to the bill's enactment pursuant to the Food, Drug, and Cosmetic Act or the Meat Inspection Act.

This would leave subject to the bill additives in use on the date of the legislation for which no "sanction or approval" had been granted. Most of these are concededly safe, or their use is based upon adequate evidence of safety. Some of them, however, may have been insuffi-

ciently tested to warrant acceptance of them as safe. The Food and Drug Administration should, therefore, be notified that they are in use and be given an opportunity to evaluate the safety and to proceed against them where such action is indicated.

It would seem reasonable, under such circumstances, to require the filing with the Food and Drug Administration, within a specified period subsequent to the effective date of the legislation, of the name, composition, and methods of use of each unapproved additive [7] in use on that date, together with such information concerning safety of the additive as is available or as the user desires to file. The Food and Drug Administration would be authorized to proceed against such substances only after a suitable warning to the user and only under previously existing provisions of law, but any additive which was not filed could be proceeded against summarily under the new legislation.

Such provisions would, it appears to me, give recognition to the fact of prior use and, at the same time, offer public-health protection by enabling the Food and Drug Administration to remove from the market any substances which might be dangerous to consumers.

Functional Value of Additives

Under the Administration bill no regulation could be issued permitting the proposed use of an additive unless such use has functional value, except that functional value could not be taken into account if the Food and Drug Administration should find that the additive was not a poisonous or deleterious substance (proposed new Section 409(b)(2)(B)(11) and (c)(3)).

Without a provision authorizing it to pass upon efficacy, the Food and Drug Administration early adopted the principle, in its administration of the provisions of the Act controlling the marketing of new drugs (Section 505),[8] that a drug is safe for use and may be administered justifiably to human beings only when it has been demonstrated that the therapeutic advantages of its use under the recommended conditions clearly outweigh the toxic disadvantages attending such use. No provision of Section 505 specifically authorizes the Food and Drug Administration to consider the efficacy or utility of a drug. The applicable statutory test under this section is basically the same as

[7] Only additives, as defined in the proposed legislation, would, of course, be subject to the filing requirement. Thus, those recognized as safe, or with respect to which there was clear and convincing evidence of safety, would be excluded.

[8] 21 USC Sec. 355.

that under the proposed definition of "chemical additive," that is, safety of use.

It may be expected that in the case of foods containing additives, which are not consumed under medical supervision as are many new drugs, a more strict requirement of evidence of safety will be imposed by the Food and Drug Administration than in the case of such drugs. In applying this test of safety, it seems reasonable to anticipate also that, even without a specific provision for the consideration of functional value, the Food and Drug Administration would take account of the advantages of use of the additive, in passing upon the question of whether it had been adequately tested for safety, as it has done in the case of new drugs under Section 505. There appears to be no language in the principal bills introduced in Congress which would prevent, in practice, the attainment of such a result.[9]

I do not refer to this application by the Food and Drug Administration of the new-drug provisions in a spirit of criticism. My purpose is only to indicate that a similar result might be expected to follow the enactment of a food-additive bill, even without the inclusion of specific authority for the Food and Drug Administration to take functional value into account. This assumes, of course, that no prohibition against the consideration of utility is enacted into law and that Congress does not disclose, in the legislative record, an intention to exclude such consideration. I suggest the likelihood of the result above outlined, despite the existence of important differentiations between the treatment of drugs under the Act and that of food additives under the proposed legislation.

The Administration bill not only contemplates, in the case of poisonous substances, a consideration of utility, but it would go further and permit the rejection of an additive solely upon the ground that sufficient functional value had not been demonstrated, without any regard to the factor of safety, and despite the fact that the additive met all reasonably applicable criteria of safety established by the statute. Such an authority goes far beyond that under the new-drug provisions as they are applied by the Food and Drug Administration.

Under the Administration bill, consideration of functional value is excluded only when the additive is not poisonous or deleterious. It is pertinent to inquire whether an additive would be regarded as

[9] In the case of the pesticide chemicals amendment, of course, usefulness is determined by the Department of Agriculture, which has developed expertise in the field of pesticides and is equipped to perform that function.

subject to the provisions of the Administration bill upon the ground that it has not been generally recognized as safe by the experts, despite the fact that it is found to be neither poisonous nor deleterious.

The policy of the Food and Drug Administration in the enforcement of existing provisions of the statute is somewhat less than reassuring with respect to the attitude which it may adopt in the matter of approval of new additives, if it is authorized to consider utility apart from safety.

Prior to the enactment of the pesticide chemicals amendment, the Food and Drug Administration had recognized that pesticidal sprays were required in the production of crops for human consumption, within the meaning of Section 406 of the Act [10] and that tolerances should, therefore, be established for them under that section, despite the fact that they are poisonous or deleterious substances. It could hardly have done otherwise in view of the legislative history of Section 406. Yet, in applying Section 406 to processed products, the tendency seems to be to think in terms of absolute necessity.

You will recall the pertinent language of Section 406(a):

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided in good manufacturing practice shall be deemed to be unsafe . . . .

It seems clear enough to me that the tests of whether an article is required in production and whether it cannot be avoided in good manufacturing practice are essentially the same. Certainly, I have found nothing in the legislative record to negative such an interpretation. It seems to be a normal and sensible reading of the language.

Why, then, for example, should a chemical subject to Section 406, whose use in the processing of agricultural produce is shown to be safe, be subjected to a more severe test than a chemical used in the growing of that produce?

It is evident that not all pesticides for which tolerances were set under Section 406(a) for use on various crops are absolutely necessary in order to permit the growing of such crops. The pesticide which is recognized as required may permit the production of a better crop or a larger yield or, perhaps, both, but ordinarily it could hardly be established that no crop at all could be produced without the chemical. The test is, therefore, in reality, whether use of the pesticide will make possible the production of definitely and substantially

[10] 21 USC Sec. 346

improved produce and, therefore, may be said to be required in an economic sense, and not whether none of the produce could be grown to maturity without it.

The use of pesticides on growing crops is of vast economic significance and vitally affects the food supply of the country. On the other hand, the use of a single chemical in a single processed food has no such basic impact. This factor should not, however, operate to negative the use of the chemical in situations where such use, under a safe tolerance, is practical and will result in a definite and substantial improvement in the usefulness of the processed or manufactured food, for—in a realistic sense and as a matter of economics—its use is then unavoidable.

Similarly, the attitude of the Food and Drug Administration toward new foods which resemble old ones does not lend encouragement with respect to the policy which it may follow where new additives or the products in which they are used are concerned. It has insisted, in effect, in recent years, that mere resemblance to the established food is sufficient to require, under the law (Section 403(c)), that a new food bear the crepe label "imitation."

Here, then, is indicated a pattern of resistance to new food products which, it seems reasonable to anticipate, will be extended to new products or new chemicals subject to the proposed food-additive legislation. If authority to pass upon functional value is specifically enacted into law, the power to broaden this pattern will be vastly increased. I do not suggest that the reason for official resistance to new products arises from a desire to preserve the market superiority of existing articles. It arises rather, I believe, from a failure to give sufficient weight to the public interest in furthering competition between new products and accepted ones and from overemphasis upon the interest of consumers in the enforcement of what many of us think are dubious interpretations of the statute. Yet the undesirable result is there, without regard to its motivation.

Statutory Review Proceedings

The Administration bill (proposed new Section 409(i) of the Act) provides for judicial review of action by the Food and Drug Administration in accordance with, and subject to, the provisions of Section 408(i),[11] the pesticide chemicals amendment. Under Section

[11] 21 USC Sec. 348(i).

408(i), the findings of the Food and Drug Administration with respect to questions of fact must be sustained if supported by substantial evidence when considered upon the record as a whole, including any report and recommendation of an advisory committee of experts appointed pursuant to subsection (g) of that section. This is, of course, the "substantial evidence" rule, as interpreted by the Supreme Court in the *Universal Camera* case.[12]

Substantial and, I believe, sound reasons have been advanced for granting to the courts a greater control over administrative determinations under food-additive legislation than is permitted under the pesticide chemicals amendment and Section 701(e) of the Act.[13] These reasons have been fully discussed both at hearings held last year on the proposed legislation and elsewhere.

Because of this viewpoint, there was general industry support for the approach in H. R. 8275,[14] one of the bills upon which the hearings to which I have referred were held. That bill contemplated pretesting by industry of additives, submission of testing data to the Food and Drug Administration and, in the event of disagreement as to whether an adequate showing of safety had been made, suit by declaratory judgment by the person submitting the data or by the Food and Drug Administration, to obtain judicial determination of the issue. Introduced in the Eighty-fifth Congress by Mr. Harris, H. R. 8390 provides for an injunction suit by the Food and Drug Administration against a person who has submitted pretesting data which is rejected as inadequate and who has notified the administration that he proposes, nevertheless, to ship the additive, or a food containing it, in interstate commerce.

It is my view that either of these devices—an action for a declaratory judgment or for an injunction—is a sound method of dealing with the problem. I do not foresee that the Food and Drug Administration would be burdened with a plethora of declaratory-judgment or injunction actions. I feel confident also that the courts are competent to deal with the scientific and technical questions which would be involved just as they have, for many years, dealt with such questions under provisions of the Food, Drug, and Cosmetic Act and other federal statutes.

[12] *Universal Camera Corporation v. NLRB*, 19 LABOR CASES ¶ 66,191, 340 U. S. 474 (1951).

[13] 21 USC Sec. 371(e), providing for court review of certain regulations issued following administrative hearing.

[14] 84th Cong., 2d Sess., introduced by Mr. Priest.

It must be recognized, however, that the opposition of both the Food and Drug Administration and the Judicial Conference of the United States to provisions for recourse to the courts for a trial *de novo*, as provided by the bills mentioned, presents a formidable obstacle to the acceptance by Congress of such provisions. It seems only prudent, under such circumstances, to develop alternatives to this type of judicial action which would provide a less restricted scope of review by the United States Court of Appeals than that proposed in the Administration bill.

It has been suggested that the scope of review or findings of fact by the United States District Court in nonjury cases, governed by Rule 52 of the Federal Rules of Civil Procedure, would be appropriate in food-additive litigation and would subject administrative determinations to a more searching review than does the "substantial evidence" test adopted in the Administration bill.

Under Rule 52, findings of the trial court may be set aside if they are "clearly erroneous." Opinions vary on the question of whether the "clearly erroneous" rule would, in fact, extend the scope of review of agency findings beyond that permissible under the "substantial evidence" test.[15] The Supreme Court has indicated, however, that the "clearly erroneous" rule permits a broader review.[16] There are authoritative commentaries supporting this view.[17] It is forcefully supported also by remarks of former Attorney General William D. Mitchell, chairman of the advisory committee appointed by the Supreme Court to draft the Federal Rules of Civil Procedure, in the course of discussions of the rules at professional meetings. Mr. Mitchell said that "in the present practice on the equity side [from which the 'clearly erroneous' rule was derived] where the findings

[15] For example, in *NLRB v. Southland Manufacturing Company*, 22 LABOR CASES ¶ 67,342, 201 F. (2d) 244 (CA-4, 1952), Chief Judge Parker and Judge Soper apparently disagreed on this point; also, Chief Justice Vanderbilt, in a comment on the Hoover Commission reports, has stated: "The substantial-evidence rule under the Administrative Procedure Act and the 'clearly erroneous' tests urged by the reports are, in practice, so nearly alike that only the scholastic mind of the hypercritical law-review writer presumes to see any real difference between them." 30 *New York University Law Review* 1268 (November, 1955).

[16] *District of Columbia v. Pace*, 320 U. S. 698 (1944).

[17] Davis, *Administrative Law* (1951), pp. 914-915 states: "According to the well-accepted theory, findings may be clearly erroneous without being unreasonable so as to be upset under the substantial evidence test; the scope of review is thus broader for a judge's findings than for findings of a jury or an agency. This basic observation was forcefully brought out in *District of Columbia v. Pace*." A similar interpretation of the significance of this case is found in Stern, "Review of Findings of Administrators, Judges and Juries: A Comparative Analysis," 58 *Harvard Law Review* 70, at pp. 84-86.

are made by a judge without a jury, on appeal, those findings may be examined and the evidence may be examined" and that the "clearly erroneous" rule permits the appellate court to consider the weight of conflicting evidence and to reverse, on the ground that the finding is "against the clear weight of the evidence." [18]

There is sound basis, therefore, for the view that if the courts of appeals were authorized to set aside administrative findings which were clearly erroneous, determinations which were against the clear weight of the evidence would be within that authority. Any question that this would be the effect of such an authorization could be resolved by a statutory provision defining the term "clearly erroneous" to mean "against the clear weight of the evidence upon the record considered as a whole."

It seems to me that adoption of the suggested provisions would substantially improve, and make more effective, the mechanism of judicial review. An example will indicate the kind of relief which such provisions should afford.

Under the substantial evidence rule, as construed in the *Universal Camera* case, it appears that a reviewing court may not "displace the . . . [administrative] choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it *de novo*." [19] Thus, where there is a difference of opinion, as to safety of an additive, between qualified industry and government witnesses at an administrative hearing, a finding based upon an adverse opinion of government witnesses may be expected to be upheld by the reviewing court. The fact that the opinion of the industry witnesses appears to the court, upon the whole record, to represent a sound point of view and to constitute the greater weight of the evidence would not, of itself, justify setting aside the administrative finding.

Such conflicts of opinion doubtless will arise in connection with the evaluation of results of animal studies and, perhaps, supporting metabolism studies, to determine the toxicity of an additive, as if, for example, government witnesses should testify, and a finding should be made, that the tests were inadequate because they had not been continued over a sufficient period of time. Although the reviewing

[18] Stern, work cited at footnote 17, at pp. 86-87. Mr. Mitchell's remarks were taken by Mr. Stern from proceedings of the Institute on Federal Rules (Cleveland, Ohio). American Bar Association and proceedings of the symposium at New York.

[19] Mr. Justice Frankfurter in *Universal Camera Corporation v. NLRB*, cited at footnote 12, at p. 488.

court may be convinced that a government finding that safety had not been established was contrary to the weight of the evidence and, therefore, clearly erroneous, it would apparently be powerless to set it aside under the substantial-evidence rule since it could not say that the finding that the tests were of insufficient duration was not supported by substantial evidence upon the record as a whole.

The proposed Code of Administrative Procedure of the American Bar Association would include within the scope of court review, in cases of adjudication, the question of whether the findings of the administrative agency are "clearly erroneous on the whole record" (Section 1009(f)). The provision for court review herein proposed for consideration would be consistent with those of the proposed Code of Administrative Procedure. They would simply go further and define the term "clearly erroneous" to mean "against the clear weight of the evidence," as it was explained by former Attorney General Mitchell.

The vast authority over the food supply proposed in the Administration bill seems clearly to justify—to my mind, to require—that an adequate review function be vested in the courts, without regard to whether that function is of the same scope as that under other provisions of the Food, Drug, and Cosmetic Act. The kind of provision proposed would not be an untested one, since it exists in current court practice and is, in essence, codified under the Federal Rules of Civil Procedure. It might be an effective alternative to the proposals which have heretofore been made on behalf of the food industry and on behalf of the Food and Drug Administration. **[The End]**

CHARLES W. CRAWFORD

In the death of Charles W. Crawford on September 15, 1957, the field of food-drug legislation and enforcement lost one of its most dedicated career men. Although Mr. Crawford had retired as Commissioner of Food and Drugs in 1954—after more than 40 years in government service—the law which he had implemented and the enforcement policies so plainly bearing the stamp of his influence continued to keep the United States "the best-fed country in the world" and assured maximum control of its drug and cosmetic products.

Mr. Crawford, a native of Texas, died at Stanford Hospital in San Francisco. He had retired to Mill Valley, a nearby suburb. His widow, a daughter and a son survive him.

We like best to remember him as a friend of the JOURNAL, and a contributor of countless excellent articles.

Public Information

UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT—IV

Mr. Janssen, Who Directs FDA Public-Information Activities, in This Part of His Study Discusses Uses of Press Releases and of Single-Issue Publications, Including Annual Reports and Also Scientific Reports and Manuals

> **"A popular government without popular information or a means of acquiring it, is but a prologue to a farce or a tragedy, or perhaps both."**—James Madison

WHEN PRESIDENT MADISON spoke of "popular information," he meant public information that is widespread and well known, and not merely available to the few who would seek it out.

Today, there is a vast amount of information about government that is technically and legally public but does not reach the public at large, or even many interested persons who may have need of it. For example, much of the official material published in the *Federal Register* is in this category.

A preceding article [1] dealt with the Food and Drug Administration's administrative or official publications. It was pointed out that additional sources of public information, such as press releases, reports, booklets, articles and speeches are needed adequately to present, explain and support a regulatory program as far reaching as that of the Food and Drug Administration. This article will be devoted to FDA activities and sources in the field of popular and scientific or technical information, as distinguished from legal or statutory publications.

Like all government agencies, FDA relies on the various channels of public communication to disseminate information. These include the general press (including radio-TV), the scientific, professional and

[1] 12 *Food Drug Cosmetic Law Journal* 229 (April, 1957).

By WALLACE F. JANSSEN

trade press, association organs, and the direct mailing of press releases and other publications to firms and individuals who have requested them.

Press Release

The most useful and widely used instrument of publicity for both government and private organizations is the press release.

A "press release" can be defined simply as any statement of public information written in newspaper style and bearing a release date. While they are prepared primarily for use by the press, government press releases serve the important purpose of providing information on a great variety of subjects whenever there is need for a clear, informal statement on any subject of interest to the regulated industry or the general public. As public information, they are available to any member of the public as well as any interested member of the press, but some releases have such limited or technical interest that they may be designated for trade or professional journals and distributed to a particular field.

The journalistic style of a release has important advantages. It is designed for clarity and brevity—easy reading and understanding. It comes to the point immediately, stating certain essential facts in the first paragraph, usually in the first sentence. It is the style universally employed by the press in the United States and other English-speaking countries. More people are accustomed to it than to any other literary form.

The release date is essential to insure fairness in the distribution of information to competing publications and business interests and to the public. "Advance releases" give more time for the purpose of

news articles based on a release. They are usually preferred by the press unless the story has high news value and is wanted for immediate publication. But the fact that a release is marked "immediate" does not mean that it has any more news importance than an advance release. Observance of release dates is perhaps the most universally respected article in the ethics of journalism.

Legal authority for press releases and other FDA publications is contained in Section 705 of the Federal Food, Drug, and Cosmetic Act, which has been previously cited.[2] Headed "Publicity," this section specifically *requires* publication of the results of all court actions under the statute, *authorizes* public warnings against imminently dangerous or grossly deceptive products, and then states: "Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department." At the time this law was passed, the Food and Drug Administration was a part of the Department of Agriculture which then had, and still has, a very broad program of public information and education. In effect, Congress said in Section 705 that there should be no restriction on public information relative to the purposes of the Act. The section is a "freedom of information" provision, but one taking into account exceptions elsewhere in the law, such as the provision to protect "trade secrets" (Sec. 301(j)).

Misconceptions Concerning Press Releases

What to put in press releases and when to issue them is within the discretion of the government agency, but this does not mean that there are no restrictions applying to government press releases. In this connection, there are some very common misconceptions.

(1) One misconception is that government press releases are "nothing but propaganda to get more power and bigger appropriations." A book could be written on the pros and cons of this proposition, but it is a fact that Congress has passed several laws to prohibit lobbying and propaganda activities by government employees. A 1913 statute [3] forbids spending money for "publicity experts" unless it is specifically appropriated by Congress. A 1919 law [4] prohibits use of any part of an appropriation for services, messages or publications designed to influence any Member of Congress in his attitude toward legislation or appropriations.

---

[2] 12 *Food Drug Cosmetic Law Journal* 93 (February, 1957).

[3] 38 Stat. 212.

[4] 41 Stat. 68.

These enactments of course do not preclude Members of Congress from seeking information and related services from a government agency, but the initiative comes from the Member. Similarly, there is no statute that prohibits a government employee or agency from responding to requests for information from the public, provided the information is not classified for national security [5] or of a confidential nature, but the request must come from a member of the public.

(2) The idea that government agencies can mail vast quantities of unwanted material to businessmen and the public is another common impression. The fact is that one cannot get on a government mailing list to regularly receive public information (except for ex-officio listings) without sending a written request.[6] Such lists are circularized regularly to find out if recipients wish to continue receiving material. If there is no response, the name is deleted from the list.

(3) Another not uncommon misconception is that much government information material is a waste of the taxpayers' money because it deals with frivolous and unnecessary subjects. The wide range of government activities which Congress has authorized is bound to yield some items of information which have only limited technical or scientific interest. It is easy to poke fun at certain government reports, and some of them probably should be given to technical journals and not published at government expense. The best insurance against abuses in this area is the certainty of vigorous criticism.[7]

(4) The impression that the press itself does not want press releases is amply disproved by the extensive use which is made of them. It is true that tired editors sometimes complain editorially about the "flood of government handouts" which they have to wade through, but tired reporters are certainly glad to use them and may even object when they learn that no release has been prepared on some topic which interests them.

(5) A related misconception is that every newspaper article concerning a government agency originated with a release of some kind or that widespread press interest in a subject indicates there was some kind of government publicity campaign to bring this about. These assumptions show unfamiliarity with the press which, despite extensive use of the so-called handouts, continues to do a great deal of enterprise

[5] 52 Stat. 8; 5 USC Sec. 631, and Executive orders promulgated thereunder.
[6] 39 USC Sec. 321(n).
[7] The classic example is a scientific report on the love life of the bullfrog. Its practical interest to the frog-leg packing industry did not save it from a barrage of ridicule.

reporting. Often, in fact, the information given in a press release is neglected by reporters who are trying to look behind it for some special and (to them) more newsworthy "angle." Putting public information "on the record," so there can be no mistake about what the government issued, is one of the important advantages of the press release.

Kinds of FDA Press Releases

In the past five or six years, the number of FDA releases has been substantially increased. These releases cover a variety of subjects as broad as the entire program of the agency. Following are some of their principal purposes, with actual releases cited as examples. Press releases may:

(1) *Call attention to proposed regulations.* They give the background of the proposals and emphasizing facts and features which may not be included in the formal notice in the *Federal Register*. Such press releases are intended to encourage public participation in the rule-making process by both industry and consumers. They are also designed to anticipate and to answer questions which may arise concerning the proposed action and, thereby, help prevent misunderstandings caused by lack of information.

Examples.—July 1, 1957—proposed standards for frozen lemonade concentrates (HEW-F49); February 16, 1957—new minimum daily requirements for niacin and riboflavin (HEW-E71); January 24, 1957—announcement of proceedings to remove four yellow colors from the list of those certified for use in foods (HEW-E55).

(2) *Report administrative action on a proposed regulation.* For example, when a final order is published, a press release may be issued to list the various changes from the original order and give the reasons for such changes—whether based on hearing testimony or on written exceptions and comments. Such a release on a long and complex regulation saves the time of the reporter, attorney and businessman, who otherwise could obtain this information only by comparing texts. Though not required to do so, FDA has made it a practice in recent years regularly to issue such releases as part of its effort to promote better understanding of the law. In effect, this type of release serves to complete the "legislative history" of a rule-making action.

Examples.—releases to drug-trade and medical journals, of September 8, 1955, and May 30, 1956, on proposed new-drug regulations.

(3) *Direct industry and public attention to the requirements of new laws and regulations.* Such a release may also tell steps necessary for compliance, give information about effective dates and describe exemptions. Of course, such facts may be included in the law or regulations, but through a press release many more persons can be informed. Often the release is the only readily available, simple statement on a complex law or amendment.

Examples.—October 26, 1951—release on passage of the Durham-Humphrey Amendment regarding drugs limited to prescription sale (FSA-D11); February 5, 1952—release to trade and professional journals on proposed regulations under the prescription-drug amendment; October 20, 1954—requirements of a new pesticide chemicals amendment to provide for safe tolerances (HEW-B60); February 27, 1957—new record-keeping requirements.

(4) *Explain some complex regulatory situation, development or action.*

Examples.—August 14, 1952—announcement of a decision by FDA, based on recommendations of a committee of medical experts, to continue certifying the antibiotic Chloromycetin, under revised directions for use (FSA-E53); February 23, 1956—release to food-industry trade journals announcing that regulations to decertify three coal-tar colors were effective with respect to all food products except oranges; reporting Congressional action to require continued certification of Red No. 32 for a limited time for coloring oranges; and reporting the substance of four court actions challenging the FDA regulation in three different appellate jurisdictions.

(5) *Announce appointments to administrative and scientific positions.* These include membership of scientific and professional advisory committees and boards, as well as consultants. Such announcements generally state the past experience and qualifications of the appointees and their responsibility and duties—information which the public is rightly entitled to have. If an advisory panel is named by another body—for example, by the National Research Council—the announcement may be made by that organization.

Examples.—January 14, 1957—appointment of a Board of Tea Experts to set new standards; November 9, 1952—appointment of consumer consultants to FDA (FSA-F6); January 17, 1955—appointment of a committee of distinguished citizens to evaluate the adequacy of en-

forcement of the federal pure food and drug laws (HEW-B82); January 2, 1957—appointments to the Food Standards Committee (HEW-E41).

(6) *Report on newsworthy scientific programs and findings.* These programs and findings are related to protection of food, drugs and cosmetics.

Examples.—January 6, 1957—announcing a continuous survey of radioactivity of selected foods (HEW-E47) (as a result of this release, FDA received more than 1,000 authentic samples of canned foods packed prior to 1945 for use in securing basic data for the survey); October 23, 1956—release to agricultural and technical journals announcing that FDA scientists had discovered marked potentiation in toxicity of certain chlorinated hydrocarbon pesticides when fed in combination to laboratory animals, and also giving notice to pesticide-chemicals manufacturers that data on potentiation should be obtained and given in future tolerance applications for such pesticides.

(7) *Warn the public against dangerous or grossly deceptive products.* These warnings, specifically authorized by statute, have been used in situations where other means of protecting the public will not be effective. For example, warning publicity may be necessary if a drug-labeling error has been made and the mislabeled packages cannot be traced quickly enough to prevent injuries. In another type of situation, if court action is not effective to remove a dangerous or grossly deceptive product from the market or if its distribution continues during prolonged litigation, FDA, acting under authority from the Secretary of Health, Education, and Welfare, may issue a formal public warning and seek the cooperation of the media of public information for its widespread distribution.

Examples.—February 12, 1957—release to medical and pharmaceutical journals warning that stem pessaries are dangerous and should be removed from the market; April 4, 1956—public warning against the Hoxsey treatment for internal cancer (HEW-D38).

Single-Issue Publications

In addition to press releases, FDA has a variety of other publications which are important sources of public information on its policies and work. These will be reviewed with brief comments:

Annual Report.—The annual report has been issued without interruption since 1907. A compilation was published in 1949 by Commerce

Clearing House, Inc., with an introduction by former Commissioner Paul B. Dunbar. Antedating these reports on enforcement of the federal food and drug laws were annual reports of the Chemist, United States Department of Agriculture, which included results of investigation into problems of food and drug adulteration.

In addition to serving as the principal historical reference, the annual reports have been a helpful source of general information on the activities and programs of FDA.

Scientific Reports.—During 1956 there were about 150 contributions to the literature on foods, drugs and cosmetics by scientists of the FDA. Many of these papers were read by their authors at scientific meetings. Reprints of scientific papers are used extensively to answer inquiries of a technical nature. Sometimes a limited number of reprints is supplied without charge by the scientific journal or they may be purchased by the government agency.

Scientific and professional journals customarily copyright their contents, and this brings up the question of the status of articles supplied at public expense. Section 7 of Title 17 of the United States Code provides that "no copyright shall subsist in the original text of any work which is in the public domain" and a decision of the Comptroller General (in Volume 22) held that the government has a proprietary interest in the writings of government personnel when such writings are prepared by such employees in their official capacity. The Public Printer has suggested that to avoid misunderstandings, publishers should be advised by those contributing such articles that the government reserves reprinting rights.

Administration scientists are encouraged to publish the results of their research work. This is regarded as a measure of their accomplishments in the public service. Publication in a recognized scientific journal is advantageous to both the scientist and the government agency. Scientific articles may also serve as the basis of news and feature treatment in other technical or popular journals reaching a wider circulation. They provide basic scientific knowledge and know-how for dealing with modern problems of food and drug protection.

Scientific Manuals.—Publication of official testing methods for foods and of official standards for drugs began before the establishment of FDA, which has not sought to enter these fields of publication. The principal source of public information on official methods of testing foods, feeds, fertilizers, and numerous other products is *Official*

Methods of Analysis, published by the Association of Official Agricultural Chemists. Standards and methods of testing official drugs are contained in the *United States Pharmacopoeia,* the *National Formulary* and the *Homeopathic Pharmacopoeia of the United States.*

The Administration also has other methods of analysis which its scientists have developed and which have not been published. It has, however, published *Microanalysis of Food and Drug Products,* listed by the Superintendent of Documents as Food and Drug Circular No. 1. In the past ten years 12,400 copies of this 175-page book were purchased by industry technologists. It is now out of print. A new 350-page edition of this text is being prepared and may be published during the 1957-1958 fiscal year. It will be extensively illustrated and will cover the entire field of microanalysis as applied to sanitary production of foods, drugs and cosmetics.

Another scientific "best seller" has been a 69-page article by Dr. Arnold J. Lehman and 11 associates on "Procedure for the Appraisal of the Toxicity of Chemicals in Foods, Drugs and Cosmetics." This was published originally in the *Food Drug Cosmetic Law Journal* of September, 1949, and revised in the October, 1955 issue. The article has been distributed without charge as a public service.

A 188-page manual, *Civil Defense Information for Food and Drug Officials,* was published in 1955, dealing with problems which would be encountered in the event of attack by chemical and biological warfare agents, and nuclear explosions and fission products. This manual was used extensively in training courses taught by FDA instructors. A new edition was issued in July, 1957.

Program Information.—Little has been done by FDA itself in the way of publishing educational literature to promote law observance in particular industries and, thus, support its enforcement programs in those industries. This lack was emphasized in the report and recommendations of the Citizens Advisory Committee on FDA.[8] An outstanding example illustrating the possibilities of such educational literature is a circular on the grain-sanitation program. This small, inexpensive leaflet dealing with the responsibilities of grain growers and dealers has been the basis of a large volume of constructive educational publicity in the farm and trade press, totaling millions of copies. Much of the progress made in improving the sanitary quality of wheat and other grains can be attributed to educational information.

[8] H. Doc. 227, 84th Cong.

Traditionally, FDA has sought and relied on the cooperation of trade associations and trade publications to promote law observance in specific situations. Outstanding benefits have resulted from this approach.

Consumer Information.—Various media have been employed over the years to disseminate information to consumers, but these efforts have been sporadic—a fact also noted by the citizens committee. In the 1920s, a highly successful series of radio talks under the title of "Read the Label" were made by FDA officials over many stations. Because of its importance in the statutory pattern of consumer protection, FDA continues to emphasize the label in its consumer-information activities. The most popular of all FDA publications as reflected in sales by the Government Printing Office is a 36-page, cartoon-illustrated booklet called *Read the Label.* Over 138,000 copies of this booklet have been printed since it was published in September, 1951. Over 81,000 of these were sold, mostly single copies at (20 cents in cash to the Superintendent of Documents).

The introduction of this pamphlet reads as follows:

> Enforcement of the Federal Food, Drug, and Cosmetic Act is a service to protect the health and pocketbook of the consumer and the operations of the law-abiding industries. The large majority of American food, drug, device, and cosmetic manufacturers are producing the safest, cleanest, most informatively labeled items ever available to the public.
>
> Today, producers labeling their goods in conformance with the law are furnishing the consumer the information he needs to be an intelligent purchaser. The Food and Drug Administration is responsible for enforcing the law. The final and essential step to achieve the maximum benefit from these activities of industry and Government is for the consumer to make practical use of the information provided on the label.
>
> The label can help you get your money's worth and guard your family's health.

The most widely circulated FDA consumer-information publication is a small leaflet of suggestions on preventing accidental poisoning in the home. Prepared by the FDA Bureau of Medicine, 70,000 copies have been printed by FDA, but reprintings of this circular, which is designed to be posted on the back of the door to the family medicine cabinet, now total at least 10 million copies. The reprints have been made available by many different organizations, including state health departments, retail druggists, hospitals, better-business bureaus and national women's magazines.

Public warnings against defective, dangerous or worthless products may also be considered "consumer information." The most widely

circulated warning ever issued by FDA was the one dealing with the Hoxsey treatment for internal cancer. In addition to nationwide press and radio coverage, this warning is also being disseminated by posters displayed in post offices and other public buildings. Over 170,000 of such posters have been distributed by the Bureau of Enforcement. Thousands of cancer victims have been dissauded from reliance on this treatment in the 15 months since the warning was issued (April 4, 1956).

Little has been accomplished as yet in the field of visual education. The citizens committee recommended production of an up-to-date documentary motion picture which can be shown on television, as well as to schools, PTA's, women's clubs, and civic organiza ions. In the meantime, use is made of two 15-minute documentary films made several years ago by RKO-Pathe and by the Proprietary Association.[9]

Since this series of articles deals with public information as issued by FDA, we make no attempt to discuss in detail many other sources from which industry and the public obtain facts and impressions regarding FDA and its mission. There is a constant flow of popular information, newspaper stories, national magazine articles, and occasional radio and TV programs, which are more or less accurate. Information-staff increases authorized by Congress should, among other things, make possible better service to the various media.

There is so much to know about modern government that the press cannot publish all of it and the public does not have time for it. This is a dilemma of modern democracy: The public must be informed, but the means of communication are inadequate and the competition for public attention is terrific. Complicating the problem is a standard of news values which often gives little emphasis to the constructive activities of government. Yet, in a nation which has freedom, there are always channels reaching groups of people who are interested in particular activities of government. The press is heterogeneous and competitive. The story worth telling—the information which needs to be published—will not be suppressed. **[The End]**

[9] Prints of "Fraud Fighters," originally produced by RKO-Pathe, are now commercially available from C & C Television Corporation, 270 Park Avenue, New York 17, New York. Prints may also be borrowed from the Food and Drug Administration for showing to live, non-paying audiences. "For Us, the Living," color film produced by the Proprietary Association, is also available on loan from FDA.

Administrative Decisions

By C. A. MORRELL

"Truly, the Administrator's Lot Is Not a Happy One," According to the Author, Who Addressed the Annual Meeting of the Division of Food, Drug, and Cosmetic Law, Section of Corporation, Banking and Business Law, American Bar Association, Held at New York University on July 12, 1957

AN ADMINISTRATOR, whether in business or government, must often make decisions. It is the sum total of these decisions and their fulfillment that makes for a good or a bad administration. In the Food and Drug Directorate many decisions are made, ranging from whether or not there is sufficient evidence to prove a violation of a law to whether a regulation is needed and how it should be stated. It is in such decisions that experience, knowledge and judgment are of paramount importance. It is well known that humans may err but we must go on making decisions if we are to carry out our functions and, indeed, if we are to live in the world at all.

Whoever is called upon to administer a law must make decisions in interpreting the meaning of the words in which the law is set forth. To do so intelligently, he must understand the intent of the law. The intent is usually clear enough, but on occasions the words used do not always express just what was in the minds of the persons under whose authority the law was enacted (for example, the Members of Parliament).

When drafting a law, legislators may not foresee all the ramifications and complications that will arise when it is put into effect. Perhaps it is not their job to do so, and that is why they accept the advice of those with experience in, and knowledge of, the field covered, although the latter may not be trained in the law. But even these experts cannot allow for every possible event in this changing world.

Furthermore, it is sometimes difficult to express an intention in terms that are broad enough to accomplish a purpose and that will not lead at some time, in some particular case, to an absurdity. It is

Dr. Morrell, of Ottawa, Is Head of the Food and Drug Directorate, Canadian Department of National Health and Welfare

surely the duty of an administrator to avoid making unreasonable demands while he is insisting that the purpose of the law be attained through its sensible and firm enforcement.

The act I have in mind when stating these rather vague generalities is the Food and Drugs Act of Canada. This act is a quite recent piece of legislation and was derived as an amendment to an act that had existed and been enforced for a good many years. The purpose of the original act was not changed, but much of the wording was changed and some new authority was added. There was hope, at the time of producing this amendment, that the new wording would clarify the meaning of various clauses, would remove some anachronistic definitions and requirements, and would arrange the subject matter in a logical and readily understood sequence. I think that, in a considerable measure, these hopes have been realized.

The act as it now is was drafted on the considered advice of administrators, scientists and lawyers, both in and out of the government service, and it underwent only a few minor changes on its journey through the Canadian Parliament on its way to becoming law. In other words, it is the result of considerable knowledge, experience and ability. Yet it does require some administrative interpretation for reasonable and proper enforcement.

I may say that when it was being drafted there was some concern expressed by those in the businesses governed by the act that certain proposed clauses should be altered to avoid the need for administrative interpretation. As a matter of fact, these clauses were so changed. I am not sure that the changes agreed upon always accomplished the

purpose intended, but this reaction of business did impress upon me the fear that was in the minds of the objectors, that the interpretations that might be put upon some of the clauses could be unfair and certainly not in their interests.

While it might have been debatable that the clauses referred to could have been subject to the interpretations feared, it is nevertheless reasonable to expect an act of Parliament to be as explicit as it is possible to make it and cover the desired scope without leaving gaps that will be used by those who may find it profitable to evade its provisions. This is a good principle, as acceptable to the civil service as it is to any others. Parliament makes the law, and it is not our wish to distort it by incongruous administrative interpretations. In most cases, of course, these distortions will be corrected by judgments of the courts.

Intent of Canadian Act

The intent of the Food and Drugs Act may be simply stated. It is to protect the Canadian consumer from health hazards and fraud in the consumption or use, and in the sale, of foods, drugs, cosmetics and medical devices. This purpose is indicated in the wording of several clauses, but perhaps most notably in that clause which confers on the governor-in-council power to "make regulations for carrying the purposes and provisions of this Act into effect . . . ." This seems to me a most suitable place in which to draw attention to the purpose of the law so that those proposing regulations will be reminded to limit them to what is justified by the law itself.

While administrative interpretation is sometimes required in enforcing regulations, there are a number of points in the Food and Drugs Act itself that must be dealt with in this way. For example, Section 4(c) states the following:

> No person shall sell an article of food that consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance.

This section was expressed in the Food and Drugs Act of 1920, in which Section 4 stated:

> Food shall be deemed to be adulterated within the meaning of this Act if it consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance . . . .

The change shown in the present clause was made to bring the wording into line with a more acceptable form from the standpoint of

criminal law and also because the application of the word "adulterated" was to be much different in the new act. Nevertheless, the purpose was the same, and considerable experience with its administration had been accumulated.

This is the sort of requirement that everyone will agree with, in principle at least. No one wants to buy food containing filthy or disgusting substances. On the other hand, it may be difficult or impossible to prepare food that is wholly free of objectionable material. The clause says "in whole or in part," and it does *not* say that the food may be sold if the part of it that is filthy or disgusting is very small. The law says that no person shall sell a food that is in part filthy and disgusting, even though the part is very small indeed.

Suppose a large import shipment of nuts was found to contain a very few that were worm-eaten and moldy. It would be unreasonable to reject the shipment for that reason alone, although the law says that, strictly speaking, it should not be sold. This situation requires administrative interpretation, and administrative tolerances have been established to permit the entry of shipments of nuts into Canada if the proportion of bad ones falls below a percentage that is quite low. I wish to emphasize that these tolerances are for administrative purposes only, and are not established by regulation. I do not believe it would be in the public interest to set such tolerances by regulation. Many shipments have been found to be well below the tolerance, demonstrating that it is quite possible to keep below the tolerance by good commercial practice. I have had requests that dealers be allowed to dilute unsatisfactory shipments by addition of nuts from good stocks so that the mixture may be acceptable. This proposal has been consistently rejected. If accepted, it would lower the quality of nuts on the Canadian market. We have not disclosed these tolerances nor do we propose to do so. It has sometimes been noted that the setting of an official tolerance or standard results in a lowering of the quality of the food concerned, in that the average quality just meets the standard set and none exceeds it by an appreciable amount. Competition and economics eliminate the better lots while the law eliminates the worst.

I would suppose that such administrative tolerances have no standing in the law. However, they are based on a knowledge of what is commonly possible and it does permit shipments that are generally acceptable as "good" to be sold while rejecting anything of an objectionably low quality.

I believe that it is much better to leave tolerances, in a case of the kind where no health hazard is involved, to the judgment and experience of administrators than to have them spelled out for the profit of the less-scrupulous merchant and for the eventual deterioration in quality of a class of food.

Reconditioning of Import Shipments

In reference to the disposal of the unsatisfactory import shipments concerned, a section of the food and drug regulations permits their entry, under the supervision of an inspector, for reconditioning in compliance with written conditions specified by a food and drug analyst. If the conditions are not carried out and the food is not reconditioned so as to comply with the requirements of the act, it must be exported or it is forfeited to the Crown.

Here, again, the decision is an administrative one. No section of the law specifies the conditions of entry in these instances. It is the judgment and experience of the analyst that must decide what they shall be. I have known cases where the analyst had given good advice to the importer, but was finally persuaded to permit entry of goods for reconditioning although he suspected that the work would be too costly or difficult to undertake. These overly optimistic importers have suffered considerable financial loss on such occasions.

You will note that the examples I have chosen are those dealing with imports. It is here that the administrator finds himself frequently in a position in which he must depend on his own judgment and experience, and in which his decision is often final. Nuts sold in Canada must meet the same requirements as do those imported into the country but, in dealing with them under Section 4(a) of the Food and Drugs Act, the administrator goes to the court, if the occasion demands, and the court decides, after hearing the evidence, whether or not the nuts are in violation of the act. The administrative tolerance may or may not help the judge reach a conclusion but it does, at least, help the administrator in reaching *his* decision to take action and in applying the law in a uniform way. This, indeed, exemplifies the need for "tolerances" or other administrative rules as a guide in enforcement programs. Without them as guides, some merchants would be treated more severely than others, and the confusion and reactions to unfair treatment would make enforcement a matter of emotions and chance rather than the orderly and objective procedure it should be.

It is not always advisable to use administrative tolerances even though the conditions on the surface appear to be the same as those involved in the interpretation of Section 4(c), which I have discussed. Section 4(a) of the Food and Drugs Act says: "No person shall sell an article of food that has in or upon it any poisonous or harmful substance."

Here, again, the wording seems to be quite clear and I would say again that I think we all agree that the intent of the section is a good one. What does one do if a food is found to contain a poisonous substance? The answer is quite clear if persons have been made ill by the consumption of such foods. What if there is no evidence that anyone has been made ill by consuming the food? The law does not say that anyone must be made ill before the substance would be considered as poisonous or harmful and it does not say that the food may contain in or upon it a tiny bit of a poisonous or harmful substance. It may not be sold if there is any such substance in or upon it.

Problem of Pesticide Residues

This raises the problem of what action to take in the case of pesticide residues. Pesticides are poisonous substances. It is their purpose to poison insects and other plant pests, and they are often poisonous to man as well. On the other hand, they are necessary in the production of an economical and abundant supply of food.

Just as for all poisons, there will be amounts of these pesticides that are so small that they will produce no effect when ingested by the human. It therefore is evident that here, again, is a place for establishing tolerances or maximum safe amounts of these substances that may appear in or upon a food used by man.

Perhaps because administrative tolerances had been established for the reasonable enforcement of Section 4(c) of the Food and Drugs Act in the case of some foods, I was asked to establish administrative tolerances for pesticides in or upon foods.

The circumstances involved in the establishment of tolerances for Section 4(a) are quite different from those in Section 4(c). In Section 4(a) we are dealing with a potential major health hazard. New pesticides are being introduced, and knowledge of their properties under the conditions of use recommended may be either inadequate or lacking. Until the necessary information is available the administrator is not justified in taking the responsibility of setting up tolerances by administrative decision. Such action would be tantamount to giving

his permission to experiment with the public as the guinea pig in the final analysis. It may be argued that the amounts of spray residues on foods ingested in such a trial would be very small and unlikely to cause harm. Anyone who really believes such a statement must know what is meant by "very small" and "unlikely to cause harm." If they know that much, they know a great deal, and the course open to them is to present their evidence so that its value may be judged by those responsible for the administration of food and drug laws containing prohibitions against the sale of foods containing in or upon them any poisonous or harmful substances. Acting on this decision, manufacturers have been advised that they must submit information and data that will permit a recommendation to be made for the establishment of a figure in the regulations setting forth the maximum amount of the toxic principle in a spray residue that may legally be left in or on a food as consumed.

A further administrative decision has had to be made in this connection. Should the maximum amount permitted (in other words, the tolerance) be just under the demonstrated safe limit for humans or should it be just large enough to permit the substance in question to be usefully employed for the purpose intended? It is obvious that if the toxicity is so great that the residue left following a proper effective use of the pesticide is dangerous, the substance is too poisonous to humans and must not be used. At the other extreme, there may be a very large gap between the residues found after effective use and the maximum amount safe for the consumer.

In dealing with this subject it has been decided to accept the axiom that no more should be used than is necessary for the purpose. Tolerances have been set up in the Canadian food and drug regulations for about 40 insecticides, following the principles of these decisions.

Lawyers will be interested to know by what authority in the act these tolerances are established. Section 24(1)(j) states: "The Governor-in-Council . . . may make regulations exempting any food from all or any of the provisions of this Act and prescribing the conditions of such exemption."

According to Section 4(a) of the act, a food having in or upon it parathion may not be sold, but such food is exempted from this prohibition by regulation B.15.002, which says:

B.15.002. Except as provided in these regulations a food named in Part I or Part II of the table herein set forth, which contains in or upon it

(a) any or all of the poisonous or harmful substances listed in Part I or Part II of the said table, in amounts not exceeding the quantities stated therein in parts per million (p. p. m.) for that food, as determined by an acceptable method, and

(b) no other poisonous or harmful substance

is hereby exempted from the provision of paragraph (a) of Section 4 of the Act.

The maximum amount of parathion permitted on foods listed in the table is one part per million. If a food is not listed, it may have no parathion on it.

There are, of course, many other administrative decisions necessary for the enforcement of an act covering such a wide field as a food and drugs act. There is, for example, one that has a bearing on the spray-residue problem and, indeed, on the whole "chemical additive" problem, as well as the introduction of new drugs. Someone has to decide on how much and what kind of evidence is necessary to establish the safety of a chemical additive or a new drug under the conditions of use recommended. This is often one of the most difficult decisions to make. Perhaps we are dealing with calculated risks, but surely these risks must be trivial before the evidence submitted may be accepted as satisfactory.

It is interesting to note that the subjects of chemical additives and antibiotics in foods will be discussed at the international level in London later this month. It is to be hoped that some more definite agreement may result from this and other international meetings and groups as to what kind of evidence and how much of it is enough to establish that a product may be safely incorporated into our food. In the meantime, we must all make our decisions on the evidence that we decide is the best available.

I find that lawyers themselves are greedy for evidence, particularly scientific evidence. Of course, someone else must supply it. They are inclined to change their approach to a case and ask for further information on this or that point. Just when the whole thing seems amply and precisely demonstrated, a lawyer will ask for something entirely different that may require weeks of work. Does the administrator decide that the whole thing isn't worth it? I will not commit myself here and now. Truly, the administrator's lot is not a happy one. **[The End]**

Federal Meat Inspection

By A. R. MILLER

The Director, Meat Inspection Division, Agricultural Research Service, United States Department of Agriculture, Presented This Paper at the 1957 American Bar Association Meeting, New York City

DISCUSSIONS of the federal meat-inspection program are usually best prefaced by some brief reference to the law under which the program is organized and to the organization of the program itself.

The Meat Inspection Act of 1906 is a good law in terms of coverage and its enabling language. It adequately provides for a program that satisfies the public interest in a clean, disease-free meat supply. It is not always recognized that the law also provides for a program that assures against adulteration and misbranding. It is important to emphasize that, in contrast with food-control programs generally, the inspection provisions of the law make it possible to integrate federal inspectors in the production lines of the meat-packing plants that are subject to the legislation.

These inspectors control the movement of animals into the slaughtering plant to make sure that only those that are fit for slaughter for human food enter the establishment. Each carcass and part handled in the slaughtering department is inspected to make sure that all diseased, contaminated, or otherwise unfit meat and meat-food products are removed from the food supply.

Inspectors supervise the preparation of manufactured meat-food products to make certain that they conform with standards of composition and bear only those labels that have been approved as being appropriate for the product and having no misleading feature.

Incidental to all of these controls, the inspectors assure proper regard for environmental sanitation.

The subject that I would like to develop more particularly here is the one that deals with the facilities requirements that relate to sanitation controls and the efficiency of the inspection. Before the meat-inspection program is inaugurated in a meat-packing plant, the structural layout and equipment facilities are required to be adequate for the maintenance of good sanitation and the application of effective inspection controls.

The meat packer sends in, with his application for the inspection, detailed plans representing the premises for which the inspection service is requested. The plans include a plot sheet which shows not only the land on which the meat-packing plant and its accompanying buildings are located, but also has a description of the surrounding premises, including the lay of the land and the kind of manufacturing or other use made of the surrounding premises. The character and surface of roadways, driveways and streets and the paving of vehicular loading areas and alleys are indicated.

Floor plans are provided showing each level in the various buildings used in the meat-packing operation. These plans show such things as the locations of walls, partitions, posts, doorways, windows, floor drainage inlets, and gutters. The plans show the conveyor systems used to transport the carcasses, parts of carcasses, and meat products. The principal pieces of equipment are also located on the plans, as well as hot- and cold-water cleanup connections and lavatory facilities. The floor drainage is particularly important, and the slope of the floors to drainage inlets is also indicated on the plans.

Plans showing cross-sections and longitudinal sections of the various buildings are furnished. These show the character and finish of floors, walls, partitions and ceilings. The principal pieces of equipment and the conveyor systems are also shown on these plans.

Exterior elevations and roof plans are provided. The exterior elevations on each side of each building show locations and sizes of doors, windows, and other openings. The roof plans show skylights, vents, and the like.

Appearing on the plans are specifications that describe such pertinent details as the source of the water supply; method of sewage disposal; description of the trapping and venting of drainage lines; hot water system; means to dispel steam and vapor in workrooms; and screens for outer openings to protect against flies.

The location of the meat-packing plant for which an application for meat inspection is pending is studied carefully. The water supply must be ample and potable. It must pass the tests prescribed for potability in the "drinking water standards" promulgated by the United States Public Health Service.

Sewage disposal in connection with operation of a meat-packing plant is a major problem. If it is intended that a municipal sewer system be used in disposing of the packing-house wastes, we want assurance that the use is in accordance with the approval of the local authorities. Similarly, if it is intended to discharge waste into a stream, this method of disposal must be acceptable to local health authorities, and it must be demonstrated that the flow of water at all seasons of the year is sufficient to carry away the sewage without creating a nuisance. The applicant furnishes letters of assurance from the appropriate local health authority concerning the sewage-disposal arrangements.

Meat-packing plants operating under federal meat inspection are required to be completely separated from any other plant and building. No connections, such as doorways, windows, stairways, elevators, passageways and loading docks, are permitted.

Applicants are encouraged, in planning their meat-packing facilities, to give consideration to probable future expansion. This sometimes influences the location of certain buildings. By planning ahead, the arrangement can be worked out whereby additional coolers, freezers, processing departments, and the like can be added at a later date in a way that will assure proper regard for sanitation and inspection control consistent with efficient production flow.

Construction

Many structural details are reviewed. It is required that floors, walls and ceilings in the various workrooms be constructed of impervious material that can be readily kept clean. The use of wood structures and wood equipment is restricted. Floors requiring drainage are to be constructed of such impervious material as dense concrete or vitrified floor brick of good quality laid on a concrete base. Interior walls are to be constructed of such materials as glazed brick, glazed tile, and smooth portland cement plaster. Ceilings are required to be smooth, flat and of good height, usually 10 feet or more.

All workrooms must be provided with adequate light and ventilation. Well-distributed artificial lighting of good quality is required in

all places where adequate natural light is not available or is insufficient. The over-all intensity of artificial illumination is required to be not less than 20 foot-candles, and 50-foot-candle illumination is required at all places where inspections are made or where special illumination is required for product manufacture.

Ventilation is provided for in all workrooms. This may be furnished either by ventilating-type windows or by mechanical means, such as fans and duct systems. Fresh air intakes for workrooms are so located that the air is not contaminated with odors, dust or smoke. Such intakes are provided with effective filters to eliminate insects and dust. They also contain heating elements for the tempering of air, if necessary in cold weather. When mechanical ventilating systems are relied on for nonrefrigerated work areas, at least six complete air changes hourly are required.

Equipment

Equipment is constructed so that it can be kept clean readily. Rust-resistent metal is the most satisfactory for this purpose. Stainless steel, of the type that has been developed for use as a food-contacting surface, is very popular. As a result of meat-inspection requirements, industry suppliers have come to use stainless steel very extensively in fabricating meat mixers, sausage stuffers, curing boxes, sausage stuffing tables, boning tables, meat hooks, and even tracks and track hangers used in meat-packing plants.

Equipment, such as soaking and cooking vats, sausage-stuffing tables, can sterilizers, and many other kinds of specialized pieces, are installed so that the waste water is delivered by means of an interrupted connection into the drainage system. Such waste water is not permitted to flow across the floor to a floor drain.

Welfare Rooms

Dressing-room and toilet facilities for food handlers require a lot of attention. The personal cleanliness of the food handler is recognized as an essential factor in the maintenance of acceptable environmental sanitation.

Well-located and properly equipped toilet and dressing-room facilities are required for each sex. The plans specify the number of employees that each such room is adequate to accommodate.

Dressing rooms are separated from adjoining toilet rooms by tight, full-height walls or partitions. A toilet room is not entered directly from a workroom but through an intervening dressing room or ventilated vestibule. Attention is given particularly to the type and location of hand-washing basins to assure their being conveniently located for the employees' use.

Space is provided where the employees can eat their lunches. Such facilities are provided with lavatory, drinking fountain, and refuse disposal. Experience has shown that failure to provide such lunch-eating facilities results in the scattering of debris throughout the processing rooms, locker rooms, and toilet facilities, thus creating an inevitable unsatisfactory condition that interferes with insect control and maintenance of sanitary conditions generally.

Facilities for Inspection

The plans show the production flow and the location and kind of equipment used in the production. These facilities are reviewed for the purpose of eliminating and correcting any awkard production flow that would interfere with sanitation controls. Equally important, the flow and volume of production must be reviewed to make certain that the inspectors and the inspection routines can be effectively integrated into the production process at the plant. Highly specialized production equipment has been developed which serves effectively the purpose of facilitating the slaughtering and meat-processing operation; this equipment provides for locating the inspector properly in the production and provides him with facilities that enable him to conduct the inspection efficiently in terms both of product control and of economical use of inspection personnel.

The layout, equipment, production flow, and volume in the slaughtering department require particular attention, as these facilities relate to the inspection routines. The production lines are geared to fast, economical operation, which requires that the inspectors and the inspection routines be integrated effectively to facilitate inspection and proper disposal of condemned product.

Well-arranged, properly equipped facilities are provided for handling and rendering inedible and condemned materials. These inedible-product departments are separated entirely from the departments where edible products are handled. Attention is given to the details

shown on the plans for these departments to assure that the condemned and inedible materials can be disposed of under strict inspection control. It is essential that the equipment in these departments be adequate to handle the volume anticipated for a particular meat-packing plant.

I have purposely taken the risk of being tedious in using considerable detail in this discussion of facilities requirements. Actually, I have hit only the high spots. A meat-packing plant is a highly specialized, extensively mechanized and fast-moving enterprise. To integrate into such an establishment an adequate system of inspection control, having the range of responsibilities specified in the meat-inspection law, requires close attention to a considerable mass of detail.

Also, my purpose in discussing in some detail the facilities requirements is to enable me to point out that each requirement is supported by a need. Only those needs are considered which bear a direct relation to the program's responsibilities under the law.

The facilities requirements are constantly under review. This comes about rather automatically as applications come in daily for approval. In each case, the applicant is represented by competent architectural and production engineers who are interested in economy and efficiency of production. Our facilities branch becomes a clearing house for new and modern structural and equipment facilities.

We like to think that the meat inspection facilities requirements, therefore, represent only that minimum which has been demonstrated to be necessary to accomplish the objectives of sanitation and inspection control. It is reassuring to find that industry itself recognizes the utility of such materials as glazed tile and stainless steel in contributing to production economy. Our experience has demonstrated time and time again that this attitude on the part of industry extends also to the other basic environmental details that I have mentioned, such as water supply, sewage disposal, welfare facilities, and light and ventilation.

As might be expected, the review of a plan for a meat-packing plant of even medium size involves a lot of hard work. Although there is sufficient similarity of operations throughout industry to permit identifying some norm for each, there is tremendous variation among meat-packing plants in kind, volume and location of the various production units.

Each plan presents a special problem or, rather, a combination of many special problems. These are reviewed with the applicant's participating engineers. The discussions proceed through a series of proposals and counter-proposals until eventually an agreement is reached and, subsequently, official approval is given the plan.

The applicant proceeds to prepare the plant in accordance with the plan. Occasionally, during this process, proposals for changes are received; they also go through a discussion process leading to official approval.

When the construction of the plant is completed and the equipment is in place, the applicant requests a survey for the purpose of determining whether the plant conforms with the approved plan. Occasionally, some adjustments are necessary at this point. Eventually, the plant is found to be in substantial conformance with the approved plans, and the inspection is inaugurated.

This subject of meat-inspection facilities requirements is extremely important because, as I know from experience, many times it is the controlling factor in a meat packer's decision to apply or not to apply for federal meat inspection. I believe many times the packer decides not to apply for the inspection because he does not understand this important phase in the processing of an application. He may even be inclined to think that the requirements do not bear a proper relation to his production interests.

In discussing these facilities requirements, I have not played down their significance in terms of cost of compliance. I have tried, however, to relate the requirements to the inspection and plant-operating needs. The cost of compliance can be justified both in terms and meeting requirements of law and in terms of improving the plant production. The applicant must, of course, balance all of these considerations when deciding whether to apply for the inspection.

We find it reassuring that some 1,300 meat-packing plants operate daily under the inspection program in compliance with the facilities requirements. These plants account for 80 per cent of the commercial production of meat in this country. They merchandise their products under the round stamp that carries the identification "U. S. Inspected and Passed." **[The End]**

CHRISTOPHER

COMMENTS

Adulteration.—An interesting decision from the First Circuit deals with a new variation in Sections 301(a) and 402(a)(3) of the Federal Food, Drug, and Cosmetic Act. A defendant was charged with the introduction into interstate commerce of adulterated turkeys. The turkeys were packed and shipped in such a way that, while not actually adulterated at the time of shipment, fecal matter within the birds would be likely to get loose and contaminate them in transit. In fact, the fecal matter did just that. Thus, the groundwork for the adulteration was laid before shipment, but actual, physical adulteration occurred during shipment; no outside agency or matter intervened.

The trial court held this to be a violation of Section 301(a). The court of appeals reversed, holding that these Sections (301(a) and 402(a)(3)) do not cover this situation and suggesting that Section 402(a)(4) (with Section 301(a)) would cover it.*

There is some question as to the soundness of the decision. I would think that Section 402(a)(4) would be subject to the same objection as the court made to Section 402(a)(3)—if not more so. The former section deals with a presently existing contamination—one existing prior to shipment; the section reads: ". . . whereby it may have become contaminated," not "whereby it may become . . . ."

I would think, too, that Section 402(a)(3) does cover the factual situation in the case, and, thus, that the court has construed the section too narrowly. The birds did contain the fecal matter and in such a way that damage likely would be done.

The case where the shipper packs fowls in such a negligent manner that they may spoil perhaps would not come under Sections 301(a) and 402(a)(3), but this is a different case. In our case, the filth is left in the birds in such a way that it is likely to contaminate the meat. The fact that the shipper manages to get the product on the train before it spoils should not be the determining factor.

* *Penobscot Poultry Company v. U. S.*, CCH Food Drug Cosmetic Law Reports ¶ 7397 (CA-1, 1957).

A COMMERCE CLEARING HOUSE PUBLICATION

For Quick Answers
to Excise Tax Problems . . .

1957 U. S. EXCISE TAX GUIDE

Designed for handy desk or brief case use, this easy-reading explanation of federal excise taxes as they stand today is well fitted to provide prompt, concise answers to everyday questions on all phases of these taxes.

Helpfully covered are such pertinent and widely varying topics as gasoline and tire taxes to finance the $30.5 billion highway program; truckers' use tax; retailers' excise taxes on jewelry and luggage; farmers' gasoline tax refunds; manufacturers' excise tax rates; latest rules on the transportation taxes and admissions taxes; and many, many more.

Supplementing the detailed explanations comprising the main body of the text are such workaday features as: tables of excise tax rates; lists of excise tax forms by subject matter and number; a Code section finding list; filled-in Form 720; and check lists of taxable and nontaxable items. Indexed; 464 pages, 6" x 9", heavy paper covers. Price $3 per copy.

Taxes and Topics Covered

- Retailers' Excise Taxes
- Manufacturers' Excise Taxes
- Facilities and Services
- Documentary Stamp Taxes
- Taxes on Wagering
- Playing Cards and Games
- Sugar, Coconut and Palm Oil
- Import Taxes
- Regulatory Taxes
- Alcohol and Tobacco Taxes
- Machine Guns and Other Firearms
- Returns, Payment of Tax, etc.

Authoritative—A Commerce Clearing House Publication

Send Orders to

CCH PRODUCTS COMPANY

BOOKS BY MAIL

4025 W. PETERSON AVE., CHICAGO 30, ILL.